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IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, *et al.*,

Petitioners,

v.

JOHNSON CONTROLS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

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JOINT APPENDIX

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CHRONOLOGICAL LIST OF RELEVANT DOCKET ENTRIES

In the Matter of: International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW, v. Johnson Controls; Case No. 84-C-0472

DATE	NR	ENTRY
04/06/84	1	Complaint; Summons issued
06/01/84	8	Answer
11/27/84	13	Affidavit of Miriam R. Horowitz in Support of Motion for Class Certification with Attached Exhibits
11/30/84	17	Affidavit of Eunice Williams
11/30/84	18	Affidavit of Beverly Tucker
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12/07/84	20	Affidavit of Donald Penney with Exhibit
02/25/85	23	ORDER; Granting Plaintiff's Motion for Class Certification
08/14/86	34	Defendant's Motion for Summary Judgment
08/14/86	36	Affidavit of Paul B. Hammond
08/14/86	37	Affidavit of Jean Beaudoin
08/14/86	38	First Affidavit of Stanley S. Jaspan
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08/14/86	40	Affidavit of Anthony Scialli
08/14/86	41	Affidavit of M. Donald Whorton
08/14/86	42	Affidavit of J. Julian Chisolm
09/10/86	46	Plaintiff UAW's Brief in Opposition to Defendant's Motion for Summary Judgment
09/10/86	47	Affidavit of Ralph O. Jones
09/18/86	48	Plaintiff's Motion to File *Instanter* Supplemental Brief in Opposition to J. Controls' Motion for Summary Judgment and Affidavit
09/18/86	49	Proposed Supplemental Brief as above

DATE	NR	ENTRY
09/18/86	50	Proposed Affidavit of Michael Silverstein, M.D.
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10/02/86	53	Third Affidavit of Stanley S. Jaspan
01/21/88	56	Decision & Order; Grants Defendant's Motion for Summary Judgment
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09/26/89		Opinion and Judgment of the United States Court of Appeals for the Seventh Circuit

[DISTRICT COURT OPINION AS AMENDED]

UNITED STATES DISTRICT COURT
E.D. WISCONSIN

No. 84-C-472

INTERNATIONAL UNION, UNITED AUTOMOBILE AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, UAW, *et al.*,
Plaintiffs,

v.

JOHNSON CONTROLS, INC.,
Defendant.

Jan. 21, 1988

As Amended Feb. 24, 1988

Miriam Horwitz, Zubrensky, Padden, Graf & Maloney, Milwaukee, Wis., for plaintiffs.

Stanley S. Jaspan, Foley & Lardner, Milwaukee, Wis., for defendant.

DECISION AND ORDER

WARREN, Chief Judge.

This case presents the issue of whether a fetal protection policy which prohibits women who are capable of bearing children from working in jobs where there is a likelihood that their blood lead [1] levels will rise above 30

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[1] A word frequently used by the experts is blood lead. Blood lead is a measure of the amount of lead that is present in the circulation where venous blood is drawn.

micrograms violates Title VII of the 1964 Civil Rights Act. Defendant, Johnson Controls, Inc. ("Johnson Controls") has filed a motion for summary judgment. After carefully reviewing all the submissions from both parties and the law on this issue, it is the Court's conclusion that the fetal protection policy at issue does not violate Title VII, and the defendant's motion for summary judgment is hereby GRANTED.

I. Background Facts

Defendant has seventeen plants in its battery division. Fourteen of these plants manufacture batteries. Lead is the principal active material used in batteries. It is the main ingredient in the paste which forms the plates of the batteries, and it forms the structure for all the conductive elements in the battery for transmitting current.

On February 25, 1985, as a result of a stipulation between the parties, the Court certified the following class: all past, present and future production and maintenance employees employed in bargaining units represented by the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW, and/or one of its Local Unions at Defendant's Battery Division plants located in Garland, Texas; Holland, Ohio; Fullerton, California; Owosso, Michigan; Louisville, Kentucky; Texarkana, Arkansas; Bennington, Vermont; Middeltown, Delaware; and Atlanta, Georgia, who have been and continue to be affected by Defendant's Fetal Protection Policy implemented in 1982.

The policy at issue was implemented in 1982 by the defendant. The policy excludes women who are capable of bearing children from working in jobs where their blood lead level will rise above 30 micrograms. Women are presumed capable of bearing children until they medically prove contrary. Women who are required to transfer out of jobs because of the policy are paid medical removal protection benefits to compensate for lost earnings. Women who are in positions where their blood lead levels do not rise to 30 micrograms are prohibited from transferring into positions where their blood lead levels will rise above 30 micrograms.

The plaintiffs allege that this policy discriminates against both women and men. Based on this policy plaintiffs allege that there is sex discrimination in recruitment and hiring, job assignments, wages, promotions and transfers within the bargaining unit, seniority, overtime, layoff and recall, demotions, on-the-job training, maternity policies, on-the-job harassment, fringe benefits, and health and safety conditions.

There is no dispute between the parties regarding the fact that excessive exposure to lead can result in significant harm to persons. There is a dispute, however, on the issues of whether there is a significant risk of harm to the fetus from lead exposure and whether that risk is substantially confined to the offspring of females, as opposed to male workers. There is also a dispute as to whether a fetus is more sensitive to lead than a postnatal child. Depositions and affidavits of experts have been submitted by plaintiffs and defendant, and the Court has closely reviewed those documents. Following is a brief summary of the testimony of the experts.

A. Expert Opinions

Dr. Anthony R. Scialli is a practicing physician and director of the Reproductive Toxicology Center. The Center serves as a source of information on the potential reproductive toxicity of environmental and physical agents. Dr. Scialli holds the opinion that because a fetus undergoes extremely rapid development of the internal nervous system during gestation, the fetus is even more sensitive to the effects of lead than a young child. Dr. Scialli further stated that damage of the central nervous system includes intellectual and motor retardation, behavioral abnormalities and deficiencies in learning abilities which may be permanent. According to the affidavit,

Dr. Scialli is aware of no studies which show that male blood lead levels of up to 50 micrograms results in any abnormality of offspring, and further that lead does not cause any change in the sperm that would be transmitted to offspring and result in abnormality in the offspring. Finally, the affidavit states that a man with a blood lead level of 50 micrograms would not have an increased risk of fathering a child with abnormalities.

Dr. J. Julian Chisolm who is a pediatrician and director of the Lead Program at the John F. Kennedy Institute set forth the following opinion:

> During pregnancy the lead in the mother's blood transfers across the placenta to the fetal circulation. The concentration of lead in the fetal tissue increases rapidly during the last trimester of pregnancy. At birth, the fetus generally has the same blood lead level as the mother. However, the fetus is medically judged to be at least as sensitive, and, indeed, is probably even more sensitive to lead than the young child. This is particularly true during the latter part of the gestation period when the central nervous system of the fetus is developing very rapidly and is extremely susceptible to the toxic effects of lead. Medical studies released in the last year or two out of Boston, Cincinnati and Port Pirie, South Australia suggest that exposure to the fetus of blood lead levels as low as 10 micrograms presents [a] grave risk of permanent harm to the central nervous system of the fetus. The risk of harm to the fetus increases proportionately with the increase of blood lead levels over 10 micrograms. Such harm includes stillbirth, reduced birth weight and gestational age, and retarded cognitive development which may result in learning deficiencies and behavioral disorders.
>
> There is no medical evidence that lead exposure to the adult, male or female, has any adverse effect on the offspring. Rather, the available medical evidence establishes that it is the exposure directly to the fetus, through the pregnant woman, which causes harm to the offspring.

Likewise, the affidavit of Paul B. Hammon, Professor of Environmental Health at the University of Cincinnati and director of a study currently being conducted in Cincinnati of the effects of lead exposure on children, stated that he was unaware of any human studies which conclude that blood lead levels of up to, and even exceeding, 50 micrograms in the adult male will cause any demonstrable effect on the development of the fetus.

The deposition of Seymore Legator, professor and director of the division of environmental toxicology was submitted wherein Professor Legator states that there is "no question that lead is hazardous to the fetus by embryo exposure" and that children are very sensitive to lead. Professor Legator also stated that lead poses a threat to both men and women, but it is still unknown about male sensitivity, but he recognized that there is a problem and that lead probably causes a genetic lesion during spermatogenesis.

Another physician, M. Donal Whortin, is the Senior Occupational Physician/Epidemologist for a company that conducts research in the areas of occupational and environmental health and is a primary medical consultant for a number of companies. Dr. Whortin holds the opinion that "the current OSHA lead standard of 50 micrograms per deciliter of whole blood should generally protect adults of either sex from significant adverse effects in the various adult systems." Dr. Whortin was a coinvestigator in a 1981 study which compared the quality of the semen of lead exposed workers with non-exposed males. The study discovered no changes in the semen quality of lead exposed workers. Nevertheless, Dr. Whortin stated that recent medical studies have shown that a fetus' central nervous system can be injured by

exposure to blood lead levels of 10 micrograms. Dr. Whortin concluded that the central nervous system of the fetus and not the reproduction systems of the male or female worker is at greatest risk.

The testimony of Charles W. Fishburn was also submitted for purposes of the motion. Dr. Fishburn is a physician and Assistant Clinical Professor at the University of Wisconsin. Dr. Fishburn is certified in occupational medicine. Occupational medicine involves the study of the relationships of injury and disease caused by chemical exposures in occupations. He states that children are particularly sensitive to lead because children do not have a barrier between the brain and the blood. Further, children develop a barrier around the age of five. Until the barrier is developed, if children ingest lead, they can be poisoned immediately. The child also can go into convulsions resulting in damage to the central nervous system.

In a fetus, the central nervous system is one of the first systems that develops and the first to be affected. A fetus gets its blood from the mother and there is no way, according to Dr. Fishburn, to protect a fetus when it is overexposed to lead. Dr. Fishburn states that damage to the central nervous system is apparently permanent.

Michael Silverstein, an Occupational-Health Physician in the Health and Safety Department of the United Auto Workers, is of the opinion that there is no evidence that reproductive risks are different for men and women at equal blood-levels. Furthermore, Dr. Silverstein states that "the toxic effects of lead exposure on human adults is similar and equivalent in impact to that observed in children at equivalent exposure levels." Dr. Silverstein discussed one study published in 1972, Hildebrand, where it was found that male rats with blood levels between 14 and 26 resulted in impotence and a decrease in sperm mobility. Dr. Silverstein stated that it could be speculated that an abnormal sperm could carry damaged genetic material which could result in damaged offspring or functional infertility.

Assistant Professor of Occupational Medicine at the University of Michigan School of Public Health, Kelly Ann Brix, states the conclusion based upon a review article, that there is a clear effect of lead upon the male reproductive tract in mammals.

Ellen Silbergeld, a toxicologist and a senior scientist for the Environmental Defense Fund, holds the opinion that all persons should not be exposed to lead levels above 12 micrograms.[2] Silbergeld also states that there is no evidence that a fetus is more sensitive than a postnatal child. Further, in animals, Silbergeld states, that high doses of lead in the first trimester can cause spontaneous abortion of an embryo. Silbergeld also stated that "a woman may be exposed to lead early in pregnancy and deficits noted in the child after birth, but those deficits might have been associated with the on-going exposure which occurred in the late stages of pregnancy . . . [because] for all purposes there is a continuing exposure to lead even after removal from sources of lead. . . ." Silbergeld estimated that if a person, after exposure to lead is placed in a lead-free environment, the turnover of lead is about 100 days, "so within a year or so there would be a reduction in lead." This time estimate according to Silbergeld is accurate in a lead-free environment, but in the absence of a lead-free environment, there is a continuing exposure to lead.

II. Prior Law

There are essentially two types of Title VII cases: Disparate treatment and disparate impact. Disparate treatment occurs when an employee has been treated less

[2] Silbergeld also states that "I think the blood leads that are called for monitoring are much too high, and I also don't understand why it applies only to women."

favorably because of sex. There are two types of disparate treatment cases: facial and pretextual. "Facial discrimination occurs when an employer adopts a policy that explicitly treats some employees differently from others on the basis of race, religion, national origin, or gender (pregnancy)." *Hayes v. Shelby Memorial Hosp.*, 726 F.2d 1543, 1547 (11th Cir.), *reh'g denied*, 732 F.2d 944 (11th Cir.1984). The only defense to a charge of facial discrimination is a bona fide occupational qualification (BFOQ). A second theory under disparate treatment occurs when the employer adopts a facially neutral policy, but which is a pretext for discrimination. A disparate impact suit exists when although a policy is neutral, it has a disparate impact on a protected class. Discriminatory motive is not required, and the defense to an allegation of disparate impact is business necessity.

Only three jurisdictions have reviewed Title VII actions involving the health of the fetus.[3] The Fourth Circuit Court of Appeals was the first circuit court to address the fetal vulnerability program in *Wright v. Olin Corp.*, 697 F.2d 1172, 1177 (4th Cir.1982). Olin Corporation instituted a fetal vulnerability policy which restricted fertile females from jobs which required con-

[3] Despite a lack of case law on this issue, many legal writers have addressed the issue. *See generally*, Comment, *Maternal Liability: Courts Strive to Keep Doors Open to Fetal Protection—But Can They Succeed?*, 20 J. Marshall L.Rev. 747 (1987); Comment, *Gender Specific Regulations in the Chemical Workplace*, 27 Santa Clara L.Rev. 353 (1987); Buss, *Getting Beyond Discrimination: A Regulatory Solution to the Problem of Fetal Hazards in the Workplace*, 95 Yale L.J. 577 (1986); Timke, *Exploring the Limits of Legal Duty: A Union's Responsibilities with Respect to Fetal Protection Policies*, 23 Harv.J. on Legis. 159 (1986); Comment, *Fetal Protection Programs under Title VII—Rebutting the Procreation Presumption*, 46 U.Pitt.L.Rev. 757 (1985); Note, *Wright v. Olin Corp.: Title VII and the Exclusion of Women from the Fetally Toxic Workplace*, 62 N.C.L.Rev. 1067 (1984); Williams, *Firing the Woman to Protect the Fetus: The Reconciliation of Fetal Protection with Employment Opportunity Goals under Title VII*, 69 Geo.L.J. 641 (1981).

tact with toxic chemicals. The Fourth Circuit determined that the disparate treatment analysis was inappropriate for this particular case because under disparate treatment, the plaintiff must show that the employer intended to treat the class less favorable. The *Wright* court stated:

> Here the claim is that the intention to "treat less favorably" is manifest in the very nature of the program and the factual defense is not truly aimed at rebutting that indisputable fact but at justifying it on the basis that the purpose behind it was benign in relation to the claimant's sex.

697 F.2d at 1185 n. 20. The court stated that the disparate impact theory with the business necessity defense was appropriate. The court held that the fetal protection policy establishes a prima facie case of discrimination. The court went on to find, however, that a business necessity defense existed in this situation by analogizing the fetus to invitees and licensees who are legitimately on the business premises. The court stated that "the safety of unborn children of workers would seem no less a matter of legitimate business concern than the safety of the traditional business licensee or invitee upon the employer's premises." 697 F.2d at 1189.

The Fifth Circuit was the next circuit to address the issue of fetal protection in *Zuniga v. Kleberg County Hospital*, 692 F.2d 986 (5th Cir.1982). In *Zuniga*, a female x-ray technician was terminated from employment because of the effects of exposure of the fetus to x-ray radiation and the concern of future liability of the hospital to the child. The Fifth Circuit found that the plaintiff rebutted the business necessity defense by showing that the hospital failed to utilize less discriminatory means. *Id.* at 992.

The next circuit to address this issue was the Eleventh Circuit in *Hayes v. Shelby Memorial Hospital*, 726 F.2d 1543 (11th Cir.), *reh'g denied*, 732 F.2d 944 (11th Cir. 1984). *Hayes* also involved a plaintiff who was a female

x-ray technician and who was fired because she was pregnant. The Eleventh Circuit reviewed the case under both the disparate treatment analysis and the disparate impact analysis. Under the disparate treatment analysis, the court did not find that an analysis of pretextual discrimination was appropriate because the plaintiff was fired because of her pregnancy. A BFOQ defense could not be established because there was no evidence that plaintiff's pregnancy would interfere with her ability to perform her job and the hospital failed to provide evidence that the level of radiation to which the plaintiff would be exposed posed an unreasonable risk of harm to the fetus.[4]

The Court, however, found that a facial discrimination analysis was proper. A presumption of facial discrimination applies to women. "That presumption may be rebutted, however, if the employer can show that although its policy applies only to women, the policy is neutral in the sense that it effectively and equally protects the offspring of all employees." *Hayes*, 726 F.2d at 1548.

The *Hayes* court went on to state that even if the employer proves that the policy is justified in a scientific basis and is not required to protect the offspring of male employees, the policy still has a disproportionate impact on women; only women are excluded from the jobs. The *Hayes* court stated that the plaintiff established an au-

[4] The *Hayes* court further noted:

> Because the Hospital failed to prove its policy was necessary we need not reach the factual issue of whether x-ray radiation affects the offspring of employees only through pregnant women, or whether similar effects can occur from exposure to males. Documents cited by amici do suggest that radiation induced mutations can pass to offspring from male sperm, but neither party developed on this issue at trial.

Hayes v. Shelby Memorial Hosp., 726 F.2d 1543, 1552 (11th Cir.), *reh'g denied*, 732 F.2d 944 (11th Cir.1984). The parties in this case have, however, submitted affidavits and depositions regarding the effects males exposed to lead and their offspring.

tomatic case of disparate impact for which the defendant must raise a business necessity defense.

The business necessity defense is generally related to job performance. The *Hayes* court recognized that fetal protection does not have any relation to job performance. The court, however, did not find that the business necessity defense does not apply, but rather found that "the defense in a fetal protection case is justified by a genuine desire to promote the health of employee offspring. . . ." *Id.* at 1552-53 n. 15. The court went on to further hold that the business necessity defense "automatically" applies because at the point where the court undertakes a disparate impact analysis, the employer "has *already* proved—to overcome the presumption of facial discrimination—that its policy is justified on a scientific basis and addresses a harm that does not affect men." *Id.* at 1553. If a business necessity defense exists, the burden then shifts to the plaintiff to show that there are no "acceptable alternative policies that would better accomplish the purposes of promoting fetal health, or that would accomplish the purpose with a less adverse impact on one sex." *Id.* In brief three elements were set forth by the *Wright* court for reviewing a fetal protection policy:

(1) that a substantial risk of harm exists;

(2) that the risk is borne only by members of one sex; and

(3) that the employee fails to show that there are acceptable alternative policies that would have a lesser impact on the affected sex.

Id. at 1554. If these three elements are met, the policy does not violate Title VII.

III. Analysis

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and

admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." A factual dispute will not preclude summary judgment unless the fact is "outcome determinative according to the governing law." *Reardon v. Wroan*, 811 F.2d 1025, 1027 (7th Cir.1987).

A. Disparate Treatment

Reviewing this case under a disparate treatment analysis results in the conclusion that the plaintiffs have established a prima facie case of discrimination because the fetal protection policy excludes women from positions which men are not excluded from. The *Hayes* court stated that there is a "*presumption* that if the employer's policy by its terms applies only to women, then the policy is facially discriminatory." 726 F.2d at 1548. This presumption is rebutted by demonstrating that there are "significant risks of harm to the unborn children of women workers from their exposure during pregnancy to toxic hazards in the workplace make necessary, for the safety of the unborn children, that fertile women workers though not men workers, be appropriately restricted from exposure to those hazards and that its program of restriction is effective for the purpose." *Wright*, 697 F.2d at 1190; *Hayes*, 726 F.2d at 1548.

In the present case, there is a disagreement among the experts regarding the effect of lead on the fetus and the effect of lead on male and female reproduction. This dispute, however, is not outcome determinative. The Fourth Circuit stated:

> To establish the requisite degree and cast of the risk of harm, it is not necessary to prove the existence of a general consensus on the points within the qualified scientific community. If suffices to show that within that community there is so considerable a body of opinion that significant risk exists, and

> that it is substantially confined to women workers, that an informed employer could not responsibly fail to act on the assumption that this opinion might be the accurate one.

The expert opinion in this case demonstrates that there is a considerable body of opinion which holds that lead is hazardous to the fetus through embryo exposure, and a fetus that is exposed to lead carries the significant risk that the central nervous system will be damaged. Further, a significant opinion exists which holds that the fetus cannot be protected when it is overexposed to lead from the mother's blood. Although plaintiffs state that today "reproduction is now largely discretionary," Dr. Ghisolm stated that many pregnancies are unplanned. It is very likely that a women could be pregnant without being aware of it. If this woman has a blood lead level of above 10 micrograms, her child could be born with abnormalities even if, after she discovers that she is pregnant, she removes herself from the lead environment because the fetus has been exposed to lead during early development when the central nervous system was developing. Also, lead remains in the body for a significant period of time. Furthermore, lead builds up in the blood, soft tissues, and bones. If the lead leaves the blood and soft tissues, lead still remains in the bones; it takes even longer for the lead to leave the bones. According to the experts, it takes about two or three times as long for the blood leads to decrease as it did for such blood levels to increase.

Further, a fetus that has been exposed to lead may be stillborn. The fetus may have a reduced birth weight and gestational age, and retarded cognitive development which may result in learning deficiencies and behavioral disorders. This is a significant and unreasonable risk of harm to the fetus. The fetal protection policy is necessary. The employer has carried its burden of "showing that the body of opinion believing that significant risk

exists is so considerable 'that an informed employer could not responsibly fail to act on the assumption that this opinion might be the accurate one.'" *Wright*, 697 F.2d at 1191.

The next step to consider is whether the hazard does not apply to the offspring of male employees. In *Hayes*, the court stated, "[i]n those instances in which scientific evidence points to a hazard to women, but no scientific evidence exists regarding men, an employer may be allowed to adopt a suitable policy aimed only at women." 726 F.2d at 1549.

Expert opinion has been provided which holds that lead also affects the reproductive abilities of men and women. Some experts hold that these effects are as great as the effects of exposure of the fetus. Although the Court believes that men, women, and fetuses should be protected from lead exposure, there is expert opinion that fetuses are subject to a greater risk because the fetuses central nervous system is developing, and further, a fetus could be exposed to lead without the mother's knowledge. One legal writer has stated that "an employer may be justified in excluding all women of childbearing capacity from working with compounds that cause reproductive injury to the female worker prior to her knowledge of pregnancy." Comment, *Gender Specific Regulations in the Chemical Workplace*, 27 Santa Clara L.Rev. 353, 370 (1987). Although adults of both sexes may be subject to equivalent susceptibility of reproduction hazards, a great body of experts are of the opinion that the fetus is more vulnerable to levels of lead that would not affect adults. The Court simply cannot overlook this possibility of severe harm only to the fetus. As a concern for society and future generations this Court must uphold the fetal protection policy. The fetus deserves special protection from lead. If women always knew when they were going to become pregnant, the mother could remove herself from the lead environment; this predictability does not

always occur with accuracy. "Unlike abortion, in which a woman makes a knowing decision to end fetal life, workplace hazards may harm a worker's reproductive system on unborn offspring without his or her knowledge or consent." Timko, *Exploring the Limits of Legal Duty: A Union's Responsibilities With Respect to Fetal Protection Policies*, 23 Harv.J. on Legis. 159, 167 (1986). Because of the fetuses possibility of unknown existence to the mother and the severe risk of harm that may occur if exposed to lead, the fetal protection policy is not facially discriminatory.[5] Further, plaintiffs have failed to establish that there is an acceptable alternative policy which would protect the fetus. Perhaps with the improved development of pregnancy testing, an alternative may develop, but even if a pregnant woman is removed from lead exposure once she is aware of the pregnancy, the lead level does not decrease as quickly as it built up; lead remains in the body for some time. Thus, the fetus would be exposed to lead even if the mother is removed from the lead environment.

Additionally, based upon the affidavits submitted, it is apparent that the company is doing all that it can to reduce lead exposure levels to safe levels. Since 1978, the defendant has spent approximately 15 million dollars on environmental engineering controls in its Battery Division Plants. Although plaintiffs state that "in the opinion of Toxicologist Ellen Silbergeld, the technology exists to reduce blood lead levels below 15 micrograms," Ms.

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[5] Because this Court has determined that the lead fetal protection policy is not facially discriminatory, this Court does not have to undertake a bona fide occupational qualification's (BFOQ) analysis. "Under traditional analysis, the BFOQ defense is available only when the employer can show that the excluded class is unable to perform the duties that constitute the essence of the job, duties that Title VII defines as 'necessary to the normal operation of the particular business or enterprise.'" *Hayes*, 726 F.2d at 1549. Although not required to address, this Court merely notes that an employee's job performance would not be affected by pregnancy.

Silbergeld's deposition transcript reveals that she is not aware that there is technology which exists that would reduce blood lead levels at Johnson Controls to 12 micrograms. Plaintiffs have failed to demonstrate that acceptable alternative policies exist.

B. Disparate Impact

Although the fetal protection policy is facially neutral, it has a disproportionate impact on women; thus, a prima facie case of disparate impact exists. The employer's only defense in this situation is a business necessity defense, but "[o]ne problem with business necessity as defined under traditional Title VII analysis, but applied in the context of an employer's fetal protection program, is the requirement that the employer's policy be related to job performance because fetal protection does not, in a strict sense, have anything to do with job performance." *Hayes*, 726 F.2d at 1552. The *Hayes* court expanded the business necessity defense to cover the fetal protection case because "the defense in a fetal protection case is justified by a genuine desire to promote the health of employee offspring. . . ." *Id.* at 1553. This Court agrees. There is a business necessity to protect fetuses. The fetus, from exposure to lead, faces a substantial risk of harm, and this exposure exists only for pregnant women. Men simply cannot expose a fetus to lead in the same way women can. The *Wright* court analogized fetuses to licensees and invitees, and stated that "[c]ertainly the safety of unborn children of workers would seem no less a matter of legitimate business concern than the safety of the traditional business licensee or invitee upon an employer's premises." 697 F.2d at 1189. In view of the fact that a significant risk exists for fetuses exposed to lead, the fetuses safety cannot be ignored. A business would not expose its customers to lead. Furthermore, although not of primary importance, a business should be able to protect itself from future lawsuits which may arise because a child was prenatally exposed

to lead. Thus, the business necessity defense applies to a lead fetal protection policy. There is a general societal interest in protecting the health of fetuses and children.

C. Toxic Substance Control Act (TSCA)

Plaintiffs argue that although there is a societal interest in fetal safety, the obligation of protecting society's interest has been delegated to the Environmental Protection Agency in the TSCA. The TSCA requires producers of chemicals to report to the EPA information about substances which pose a substantial risk. The EPA is required to take regulatory action within 180 days after receiving information that a substantial risk may exist. If the EPA determines that a substantial risk exists, the EPA can regulate the substance. One commentator has criticized the effectiveness of the Act:

> Despite its broad scope, TSCA's usefuless in dealing with fetal toxins, teratogens, and mutagens has been limited. The EPA has substantial discretion under the statute, and the agency has tended to exercise this discretion to avoid active regulation. The EPA has announced that it intends to regulate at most two or three substances per year, with relevant studies taking up to two years per substance to prepare. The Office of Management and Budget under the Reagan administration has been relentless in criticizing the EPA's modest efforts to regulate dangerous chemicals. Consequently, fetal toxins, mutagens, and teratogens have escaped regulatory review.

When the EPA does examine a chemical, it may consider the availability of substitutes and the economic consequences of regulation before making a pre-regulation determination that the chemical poses an "unreasonable risk." Furthermore, the promulgation of regulations involves consideration not only of their economic consequences but also of the avail-

able level of technology. A consideration of both these factors would probably lead to an acceptance of hazards that may not pose significant risks to employees but do pose grave risks to their unborn children.

Timko, *supra*, p. 16, at 172. Based upon the foregoing, the Court is not persuaded that the TSCA is protecting fetuses from lead exposure. Furthermore, eliminating the use of lead in battery production has not yet been achieved. The use of lead is still necessary at this point. The company is, however, continuing to "study, develop, and implement engineering controls to reduce the lead exposure and blood lead levels of all employees." Beaudoin Affidavit, ¶ 17. Although no evidence has been presented to the Court demonstrating that the EPA has reviewed the lead situation at issue here, it is unlikely that the EPA would prevent the use of lead in the absence of a substitute. Further, because the TSCA is gender neutral, it would fail to protect the fetus which faces a significant risk from lead exposure because male and female are treated equally under the Act.

IV. Conclusion

Society has an interest in protecting fetal safety. Lead poses a substantial risk of harm to the fetus. This risk is born only by women who are pregnant or will become pregnant. The plaintiffs have not shown that there is an acceptable alternative that would have a lesser impact on females. Johnson Controls fetal protection policy does not violate Title VII. Stillbirths, reduced birth weight and gestational age, and retarded cognitive development are abnormalities too serious for this Court to find unimportant.

Defendant's motion for summary judgment is hereby GRANTED.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

Case No. 84-C-0472

INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, UAW and its LOCAL UNIONS Nos. 12, 119, 509, 754, 1283, 1343, 1371, 1516, and 1719, and LOIS SWEETMAN, LINDA BURDICK, ELSIE NASON, MARY ESTELLE SCHMITT, SHIRLEY JEAN MACKEY, MARY CRAIG, ANNA MAY PENNEY and DONALD PENNEY, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

JOHNSON CONTROLS, INC.,

Defendant.

COMPLAINT

I.

JURISDICTION

1. The jurisdiction of this Court is invoked pursuant to 42 USC § 2000e-5(f), USC § 1337, and 28 USC § 1343(3), (4). This action is brought to remedy discrimination because of sex in terms, conditions and privileges of employment, hiring and compensation in violation of federal statutes. The action arises under Title VII of the Civil Rights Act of 1964, 42 USC § 2000e, *et. seq.*

2. The unlawful practices alleged herein have been promulgated by the defendant company, Johnson Controls, Inc., throughout its Globe Battery Division.

3. Venue herein is proper, as defendant, Johnson Controls, Inc., (hereinafter "the Company") has its principle place of business in Milwaukee, Wisconsin.

4. The plaintiffs, International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW (hereinafter "UAW"), and its Local Union Nos. 12, 119, 509, 754, 1283, 1343, 1371, 1516, and 1719, duly filed a charge with the EEOC alleging that the defendant company has, through the implementation of its so-called "Fetal Protection Policy," discriminated on the basis of sex against all females in hiring, wages, terms, conditions, and privileges of employment. Further, the UAW alleged the Fetal Protection Policy discriminates against male employees on the basis of sex by failing to provide reproductive health hazard protections equal to those provided to female employees.

5. The plaintiffs, Lois Sweetman, Linda Burdick, Elsie Nason, Mary Estelle Schmitt, Shirley Jean Mackey, Mary Craig, Anna May Penney and Donald Penney each duly filed charges against defendant Johnson Controls, Inc., with the Equal Employment Opportunity Commission (hereinafter "EEOC") complaining of the various acts of sex discrimination committed by defendant pursuant to its "Fetal Protection Policy." The plaintiffs were each notified by the EEOC, pursuant to Section 706(f)(1) of the Civil Rights Act of 1964 as amended, 42 USC § 2000e-5(f)(1) of their right to institute suit. The dates of notice of right-to-sue are as follows:

Name of Plaintiff	Date Right-to-Sue Letter Received
Lois Sweetman	1/12/84
Linda Burdick	3/22/84
Elsie Nason	3/22/84
Mary Estelle Schmitt	3/22/84
Shirley Jean Mackey	3/22/84
Mary Craig	3/22/84
Anna May Penney	3/22/84
Donald Penney	3/22/84
UAW	3/22/84

6. This Complaint has been filed within ninety (90) days of the receipt of said notice of Right-To-Sue letters.

7. All conditions precedent to the institution of this lawsuit have been met.

II.

PARTIES

8. The plaintiff, International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW, is a labor organization engaged in an industry affecting commerce within the meaning of 42 USC § 2000(d), (e) and exists, in whole or in part, for the purpose of dealing with the company concerning grievances, labor disputes, wages, rates of pay, hours, and other terms and conditions of employment. The UAW has more than 25 members.

9. Together with its local unions, the UAW is the collective bargaining representative of employees at the following facilities owned and/or operated by defendant Company: Owosso, Michigan, Plant and Clerical Units; Louisville, Kentucky, Plant and Clerical Units; Bennington, Vermont; Atlanta, Georgia; Dallas, Texas; Fullerton, California; Texarkana, Arkansas; Middletown, Delaware.

10. The UAW is a "person" within the meaning of 42 USC § 2000e-(a). The UAW's heaquarters are located at 8000 East Jefferson Avenue, Detroit, Michigan 48214.

11. UAW Local Unions Nos. 12, 119, 509, 754, 1283, 1343, 1371, 1516 and 1719 each represent bargaining units of Johnson Controls, Inc., Globe Battery Division employees. Each local union is a labor organization engaged in an industry affecting commerce within the meaning of 42 USC § 2000e-(d)(e), and represents employees at the below-specified facilities for the purpose of dealing with the defendant concerning wages, hours

and other terms and conditions of employment. Each Local Union is a "person" within the meaning of U.S. § 2000e-(a).

(a) Local Union No. 12, at 2300 Ashland Avenue, Toledo, Ohio 43620, represents production and maintenance employees at the Company's plant in Holland, Ohio.

(b) Local Union No. 119, at 3100 West Walnut—Apt. 233-11, Garland, Texas 75042, represents production and maintenance workers at the Company's plant in Garland, Texas.

(c) Local Union No. 509, at 2432 Kellogg Park Drive, Pamona, California 91768, represents production and maintenance workers at the Company's plant in Pamona, California.

(d) Local No. 754, at 1824 Corunna Avenue, Owosso, Michigan 48867, represents production and maintenance workers and office/clerical technical workers at the Company's plant in Owosso, Michigan.

(e) Local Union No. 1283 at 5505 Walnut Way, Louisville, Kentucky 40229, represents production and maintenance workers at the Company's plant in Louisville, Kentucky.

(f) Local Union No. 1343, at 2412 Mamie, Texarkana, Texas 75501, represents production and maintenance workers at the Company's plant in Texarkana, Arkansas.

(g) Local Union No. 1371, at Silk Road, Bennington, Vermont 05201, represents production and maintenance employees at the Company's plant in Bennington, Vermont.

(h) Local Union No. 1516, at P.O. Box 241, Middletown, Delaware 19709, represents production and maintenance employees at the Company's plant in Middletown, Delaware.

(i) Local Union No. 1791, at 459 Utoy Circle, Atlanta, Georgia 30331, represents production and maintenance employees at the Company's plant in Atlanta, Georgia.

12. Plaintiffs Lois Sweetman, Linda Burdick, Elsie Nason, Mary Esteile Schmitt, Shirley Jean Mackey, Mary Craig, Anna May Penney and Donald Penney, are all employees of the company.

13. Plaintiff Lois Sweetman is a citizen of the United States and a resident of Golts, Maryland. She has been employed at the Company's Globe Battery Division Delaware plant for approximately four and one-half years, and is a member of UAW Local 1516.

14. Plaintiff Linda Burdick is a citizen of the United States and a resident of Pound, Vermont. She has been employed at the Company's Globe Battery Division Vermont plant for approximately four and one-half years and is a member of UAW Local 1371.

15. Plaintiff Elsie Nason is a citizen of the United States and a resident of Hoosick Falls, New York. She has been employed at the Company's Globe Battery Division Vermont plant for approximately eleven and one-half years, and is a member of UAW Local 1371.

16. Plaintiff Mary Estelle Schmitt is a citizen of the United States and a resident of Cambridge, New York. She has been employed at the Company's Globe Battery Division Vermont plant for approximately four and one-half years, and is a member of UAW Local 1371.

17. Plaintiff Shirley Jean Mackey is a citizen of the United States and a resident of Atlanta, Georgia. She has been employed at the Company's Globe Battery Division Georgia plant for approximately five and one-half years, and is a member of UAW Local 1791.

18. Plaintiff Mary Craig is a citizen of the United States and a resident of Newark, Delaware. She has

been employed at the Company's Globe Battery Division Delaware plant for approximately fourteen and one-half years and is a member of UAW Local 1516.

19. Anna May Penney is a citizen of the United States and a resident of Middletown, Delaware. She has been employed at the Company's Globe Battery Division Delaware plant for approximately twelve and one-half years and is a member of UAW Local 1516.

20. Donald Penney is a citizen of the United States and a resident of Middletown, Delaware. He has been employed at the Company's Globe Battery Division Delaware plant for approximately one and one-half years, and is a member of UAW Local 1516.

21. Each of the individually named plaintiffs is a member of a Johnson Controls, Inc., Globe Battery Division bargaining unit represented by the UAW, and one of the UAW Local Union.

22. There have been collective bargaining agreements in effect between the UAW and the defendant Company at all times material to the instant suit.

23. The defendant Company, Johnson Controls, Inc., is, and has been at all times relevant herein an employer within the meaning of Title VII of the Civil Rights Act of 1964, ("Title VII") as amended, 42 USC 2000e-(b), (g), and (h). At all times herein relevant, the Company has been and continues to be subject to the provisions of Title VII. It is engaged in an industry affecting commerce and manufactures and distributes batteries in interstate commerce.

24. The Company is incorporated and exists under the laws of the State of Delaware.

25. Defendant's corporate headquarters are located at 5757 North Green Bay Avenue, Milwaukee, Wisconsin 53201.

III.

CLASS ACTION

26. The UAW, its local unions, Lois Sweetman, Linda Burdick, Elsie Nason, Mary Estelle Schmitt, Shirley Jean Mackey, Mary Craig, Anna May Penney and Donald Penney, sue individually and representatively on behalf of a class of all employees similarly situated, pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure. The plaintiffs represent a class of all past, present and future employees of the defendant Company at any of its Globe Battery Division facilities, with two sub-classes, one consisting of all past, present and future female employees and others consisting of all past, present and future male employees, who have been and continue to be or might be adversely affected by the practices complained of herein.

27. This action meets the requirements for maintenance as a class action pursuant to Rule 23(a) and (b)(1) and (2) of the Federal Rules of Civil Procedure.

28. The class and sub-classes represented are so numerous that joinder of all members is impracticable.

29. Upon information and belief, no other member of the class has instituted a similar action.

30. The questions of law and fact presented by the plaintiffs as hereafter set forth are common to the class.

31. Defendant maintains a single division-wide "Fetal Protection Policy" which discriminates on its face and as applied on the basis of sex.

32. The claims of the representative plaintiffs are typical of the claims of the class.

33. The representative plaintiffs will fairly and adequately protect the interests of the class.

34. The claims and interests of the plaintiffs do not conflict with the interests of any other members of the class.

35. The prosecution of separate actions by individual members of the class will create a risk of inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the defendant Company.

36. The Company discriminates on the basis of sex in hiring, wages, hours and terms of employment, through the implementation and continuance of its division-wide "Fetal Protection Policy." Defendant Company has acted or refused to act on grounds generally applicable to the class, or the relevant sub-class, thereby making appropriate final injunctive relief and corresponding declaratory relief with respect to the class as a whole.

IV.

FACTS

37. On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which it thereafter announced to its Globe Battery Division plants and to the unions representing workers at its Globe Battery Division plants.

38. The "Fetal Protection Policy" requires the removal from high lead exposure areas of all women capable of reproducing and the implementation of lead exposure reduction procedures. Women are presumed capable of childbearing until they medically prove the contrary.

39. Since August 9, 1982, the Company has begun implementation of its "Fetal Protection Policy" at each of its facilities. The policy remains in force at the Company's facilities continuously to the present time.

40. The "Fetal Protection Policy" constitutes an overt sex based classification which has an adverse impact on

both female and male employees on the basis of gender. On its face and as applied, the Company's "Fetal Protection Policy" constitutes discriminatory treatment and causes discriminatory effects on the basis of sex.

41. In particular, the "Fetal Protection Policy" discriminates on the basis of sex as defined by the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964, Section 701(k), and violates Sections 703(a)(1) and (2) of Title VII.

42. Pursuant to its "Fetal Protection Policy," the Company discriminates against both women and men on the basis of sex. This sex discrimination includes but is not limited to sex discriminatory treatment in:

a. recruitment and hiring;

b. job assignments;

c. wages;

d. promotions within the bargaining unit;

e. transfers within the bargaining unit;

f. seniority;

g. overtime;

h. layoff and recall;

i. demotions;

j. on-the-job training;

k. maternity policies;

l. on-the-job harassment;

m. fringe benefits;

n. health and safety conditions.

43. Until recent years, the Company has discriminated on the basis of sex in hiring. Consequently, the percentage of women workers is under 10% in each of its production and maintenance bargaining units.

44. On information and belief, following the promulgation of the "Fetal Protection Policy" the Company

has stopped hiring "women of childbearing capability" at all of its Globe Battery Division manufacturing facilities.

45. The percentage of female employees at the Company's production facilities has not increased since the promulgation of the "Fetal Protection Policy."

46. Pursuant to the "Fetal Protection Policy," defendant Company discriminates on the basis of sex in making job assignments. Women of childbearing capability are discouraged from bidding under the collectively bargained promotion and transfer system into jobs in leaded areas.

47. If women do bid on lead exposure jobs, they are denied the job and it is awarded to a male, contrary to the seniority system, in violation of the collective bargaining agreement.

48. The defendant Company discriminates against women already holding jobs in leaded areas. They must wear respirators while working, are transferred out of jobs and are kept from returning to their jobs at lower blood lead levels than similarly situated male workers.

49. Because female employees are excluded from many of the jobs at defendant Company's production facilities, pursuant to the "Fetal Protection Policy," they are denied equal opportunity for promotion, overtime, transfer, and on-the-job training. They are also subject to layoff and recall outside the seniority system because they are not allowed to exercise rights to positions in lead exposure areas.

50. The Company has and continues to violate the general duty clause of the Occupational Safety and Health Act (OSHA), 29 U.S.C. § 654(a)(1), in failing to provide a reproductively safe and healthy working environment for its female workers, rather than removing them from the hazard.

51. The Company's "Fetal Protection Policy" is in non-compliance with the OSHA lead standard, 29 CFR § 1910.1025 *et. seq.*

52. The Company's "Fetal Protection Policy" discriminates against male workers in that it denies them equally clean, safe and free from hazard, terms and conditions of employment compared to women. In particular, fertile males are subjected to greater hazards to their reproductive health than are similarly-situated women. Male employees seeking to take precautionary steps to protect their reproductive capabilities are treated less favorably than similarly-situated women.

53. The Company's "Fetal Protection Policy" discriminates against male workers in terms of placement, assignment, promotion, and/or transfer to low lead exposure jobs because current women employees, under certain circumstances, are given preferential treatment regarding placement in low lead exposure jobs.

54. The Company has and continues to violate the general duty clause of the Occupational Safety and Health Act (OSHA), 29 U.S.C. § 654(a)(1), in failing to provide a reproductively safe and healthy working environment for its male employees.

55. The Company's "Fetal Protection Policy" is in non-compliance with the OSHA lead standard, 29 C.F.R. § 1910.1025 *et. seq.*

56. Named plaintiff Lois Sweetman was transferred from her position as C.O.S. loader to a job in the Formation Section, pursuant to the "Fetal Protection Policy."

57. If Ms. Sweetman had been a male she would not have been transferred at so low a blood lead level.

58. Since then Ms. Sweetman's blood lead level has decreased further still, but she has not been allowed to returned to her job as a C.O.S. loader.

59. If Ms. Sweetman were a male worker she would have been allowed to return to her job in a leaded area when her blood lead level decreased.

60. Ms. Sweetman filed charges of discrimination with both the Delaware Department of Labor, Anti-Discrimination Section and the EEOC.

61. On January 24, 1984, the Delaware agency issued a determination finding probable cause to believe that the Company discriminated against Ms. Sweetman with respect to her sex.

62. The Company informed named plaintiff Linda Burdick that because of the "Fetal Protection Policy" she, as a fertile female, would not be allowed to work in a "leaded" area.

63. Ms. Burdick has been discouraged by the Company from bidding on jobs in leaded areas.

64. If the Policy was not in effect, Ms. Burdick would have bid on jobs in leaded areas as they became available.

65. Ms. Burdick has been denied job opportunities on the basis of her sex.

66. Named plaintiff Elsie Nason was involuntarily moved from her job of four years as a site terminal welder because of the lead in the area.

67. Even though she is fifty years old and divorced, Ms. Nason is considered "a woman of childbearing capability" by the Company, under its "Fetal Protection Policy."

68. If Ms. Nason were a male she would not have been transferred.

69. Named plaintiff Mary Estelle Schmitt was denied a job in Quality Control, which had just become available, and for which she had placed two advance bids in 1982.

70. Ms. Schmitt was told by the Company that as a fertile female she cannot work in a leaded area.

71. The job Ms. Schmitt sought was given to a male with nearly one and one-half years less seniority.

72. Named plaintiff Shirley Jean Mackey was transferred from her job as a C.O.S. loader to a non-lead area job, that of container punch operator.

73. If Ms. Mackey were a male she would not have been transferred.

V.

INJURIES

74. By its continuous and division-wide implementation of the "Fetal Protection Policy," the Company has discriminated on the basis of sex in wages, terms, conditions and benefits of employment in violation of Sections 703(a)(1) and (2) of Title VII, 42 U.S.C. § 2000e-2(a)(1) and (2), and has inflicted and will continue to inflict irreparable injury upon plaintiffs and the class they represent.

75. As a result of the unlawful discriminatory acts of the Company, all past, present and future female employees have been and continue to be subjected to irreparable injury, including but not limited to the following:

a. They have been deprived of equal job security regarding jobs in leaded areas.

b. They have been denied equal opportunity for advancement and promotion regarding jobs in leaded areas.

c. They have been denied equal access to many higher paying jobs because of being frozen out of jobs in leaded areas.

d. They have been denied job satisfaction and training equal to that of male workers in leaded ares.

e. They are subject to layoff in violation of the protections of the seniority system.

f. They are denied recall rights based on seniority.

g. They are subject to embarrassment and humiliation because their private reproductive functions are made a public issue, without their consent.

h. When permitted to work in leaded areas, female employees must suffer the discomfort of wearing respirators at lower blood lead levels than male workers.

i. When removed from jobs in leaded areas, female employees often lose additional incentive pay.

j. The atmosphere of insecurity and hostility toward women created by the Company, may well cause some to quit, and others to be sterilized to escape the unlawful policy.

k. By removing women rather than cleaning up the workplace, the employer is violating their equal rights to a reproductively safe work environment under the Occupational Safety and Health Act, 29 U.S.C. § 654(a)(1).

l. Female employees are harassed and intimidated by the Company's explicit declaration that women workers are not wanted at the Company's production facilities.

76. Female workers also suffer less earnings, including incentive and overtime pay, as well as straight time rates, because of the Company's discriminatory policy.

77. As a result of the unlawful, discriminatory acts of the Company, all past, present and future male employees have been and continue to be subjected to irreparable injury, including but not limited to the following:

a. Male employees are denied equally clean, safe and free from hazard, terms and conditions of employment compared to female employees;

b. Male employees are not given the same preferential placement treatment as female employees removed from jobs in leaded areas pursuant to the "Fetal Protection Policy."

c. Male employees desiring to reproduce are subjected to less favorable treatment than similarly-situated females and they are denied their right to a reproductively safe and healthy workplace under OSHA.

78. All present and future employees have been and continue to be subject to irreparable injury by the Company's refusal to hire women, including but not limited to being deprived of their right to an integrated work environment.

79. The above unlawful employment practices have inflicted, and will continue to inflict injury on named plaintiffs Lois Sweetman, Linda Burdick, Elsie Nason, Mary Estelle Schmitt, Shirley Jean Mackey, Mary Craig, Anna May Penney and Donald Penney, including but not limited to the following:

a. Lois Sweetman's loss of her job in a leaded area, has deprived her of opportunity, income and job satisfaction;

b. Linda Burdick was discouraged from bidding on jobs in leaded areas, suffering attendant loss of employment opportunity and income;

c. Elsie Nason was removed from her job in a leaded area, suffering loss of employment opportunity, income and job satisfaction;

d. Mary Estelle Schmitt was denied the job she bid on and was contractually entitled to, suffering loss of employment opportunity, income, job satisfaction and collectively bargained for rights under the seniority system;

e. Shirley Jean Mackey's removal from her job in a leaded area has deprived her of employment opportunity, income and job satisfaction;

f. The Company's creation of an atmosphere of insecurity regarding the continued employment of fertile females so severe that Mary Craig believed the only way she would be guaranteed continued employment at the Company was to be surgically sterilized, caused her to undergo that medical procedure;

g. Anna May Penney has been kept on a respirator at lower blood lead levels than a male, suffering loss of job satisfaction and discomfort;

h. Donald Penney has been required to work in leaded areas at a higher blood lead level than a female would be allowed to work in, causing him a loss of equally clean, safe and free from hazard terms and conditions of employment.

80. By its "Fetal Protection Policy," the defendant Company has inflicted and will continue to inflict irreparable injury on the UAW and its membership in violation of Title VII unless this Court grants relief, including but not limited to the following:

a. By refusing to hire women of childbearing capacity following implementation of the "Fetal Protection Policy," the Company has denied the union and its members the benefits of female membership and association, as well as their right to a sexually integrated workforce;

b. By refusing to promote, and/or transfer women into jobs in leaded areas, the Company has denied the Union and its members the benefit of having female members in numerous positions on the job, and their right to a sexually integrated workplace;

c. The Company, in refusing and failing to end sex discrminatory policies and practices is subjecting the UAW to the future possibility of lawsuits by female employees or applicants for failure to correct said unlawful employment practices, and is subjecting the

union's current membership to the risk of remedies for future discriminatees, which may impair, modify, amend or otherwise adversely affect the collective bargaining agreements and the employees' rights thereunder.

81. The plaintiffs and the class they represent are suffering and will continue to suffer irreparable injury if no relief is granted against defendant Company's unlawful acts and practices as set forth herein.

82. A multiplicity of suits will result if the relief herein requested is not afforded in a class action.

83. The plaintiffs have no plain, adequate remedy at law to redress the wrongs alleged herein, and this suit is the only means of securing relief.

VI.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray that this Court grant the following:

A. That this Court advance this matter on the docket, order a speedy hearing at the earliest practicable date, and cause this case to be in every way expedited.

B. That this Court enter preliminary injunctive relief enjoining the defendant Company, its officers, agents, employees, successors, assigns, and all persons in active concert or participation with it, from engaging in the discriminatory policies and practices complained of above, pursuant to the Company's "Fetal Protection Policy," including but not limited to the following:

1. Enter an order enjoining the Company from failing or refusing to promote or transfer females into jobs in leaded areas;

2. Enter an order enjoining the Company from removing females from jobs in leaded areas at blood lead levels lower than that at which males are removed;

3. Enter an order enjoining the Company from placing women workers on respirators at blood lead levels which are lower than those at which men are placed on respirators;

4. Enter an order compelling the Company to nondiscriminatorily hire, assign, transfer and promote all females, fertile or infertile;

5. Enter an order compelling the Company to nondiscriminatorily apply all terms and conditions of employment, including but not limited to those provided for in the applicable collective bargaining agreements;

6. Enter an order mandating that Lois Sweetman be returned to her job as a C.O.S. loader with full back pay and benefits;

7. Enter an order mandating that Linda Burdick be afforded the opportunity to bid on jobs in leaded areas;

8. Enter an order mandating that Elsie Nason be returned to her job as a site terminal welder with back pay and benefits;

9. Enter an order mandating that Mary Estelle Schmitt be promoted to the next opening in her plant for a Quality Control Auditor, with full back pay, front pay and all benefits;

10. Enter an order mandating that Shirley Jean Mackey be returned to her job as a C.O.S. loader with back pay and benefits.

11. Enter an order mandating damages to Mary Craig for mental distress, emotional pain and suffering and the loss of her reproductive capabilities.

12. Enter an order mandating that Donald Penney be provided the same equally clean, safe and free from hazard terms and conditions of employment as would a fertile female;

13. Enter an order mandating that Anna May Penney be placed on a respirator only at the same blood lead levels as would a male;

14. Enter an order prohibiting company layoffs and/or recalls on the basis of the "Fetal Protection Policy," limiting layoffs and recalls to the contractually-mandated date-of-hire seniority system;

15. Enter an order enjoining the Company from maintaining or continuing the policies and practices of denying, abridging, withholding, conditioning, and limiting or otherwise interfering with the rights of plaintiffs and the classes they represent as provided under Title VII.

C. That this Court grant permanent injunctive relief enjoining the defendant Company, its officers, agents, employees, successors, assigns, and all persons in active concert or participation with it, from engaging in the discriminatory practices complained of above, including but not limited to the following:

1. Enter an order enjoining the Company from failing or refusing to promote or transfer females into jobs in leaded areas;

2. Enter an order enjoining the Company from removing females from jobs in leaded areas at blood lead levels lower than that at which males are removed;

3. Enter an order enjoining the Company from placing women workers on respirators at blood lead levels which are lower than those at which men are placed on respirators;

4. Enter an order compelling the Company to nondiscriminatorily hire, assign, transfer and promote all females, fertile or infertile;

5. Enter an order compelling the Company to non-discriminatorily apply all terms and conditions of employment, including but not limited to those provided for in the applicable collective bargaining agreements;

6. Enter an order mandating that Lois Sweetman be returned to her job as a C.O.S. loader with full back pay and benefits;

7. Enter an order that Linda Burdick be afforded the opportunity to bid on jobs in leaded areas;

8. Enter an order mandating that Elsie Nason be returned to her job as site terminal welder with back pay and benefits;

9. Enter an order mandating that Mary Estelle Schmitt be promoted to the next opening in her plant for a Quality Control Auditor, with full back pay, front pay and all benefits;

10. Enter an order mandating that Shirley Jean Mackey be returned to her job as a C.O.S. loader with back pay and benefits;

11. Enter an order mandating damages for Mary Craig for mental distress, emotional pain and suffering and the loss of her reproductive capabilities;

12. Enter an order mandating that Donald Penney be provided the same equally clean, safe and free from hazard terms and conditions of employment as would a fertile female;

13. Enter an order mandating that Anna May Penney be placed on a respirator only at the same blood lead levels as would a male;

14. Enter an order prohibiting Company layoffs and/or recalls on the basis of the "Fetal Protection Policy," limiting layoffs and recalls to the contractually-mandated date-of-hire seniority system.

15. Enter an order enjoining the Company from maintaining or continuing the policies and practices of denying, abridging, withholding, conditioning, and limiting or otherwise interfering with the rights of plaintiffs and the classes they represent as provided under Title VII.

D. That this Court declare the aforesaid "Fetal Protection Policy" to be unlawful and in violation of Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000-e, *et. seq.*

E. That this Court enter a judgment against the defendant Company and in favor of each named plaintiff to make them monetarily whole for lost past, present and future pay and benefits each has suffered or will suffer as a result of the Company's unlawful employment practices.

F. That this Court enter a judgment against the defendant Company requiring defendant to make whole those persons adversely affected by the unlawful practices described herein by providing appropriate monetary relief with interest, in an amount to be proved at trial herein, including but not limited to the differential pay and benefits received by members of the class on their present jobs and the pay and benefits they would have received had they not been unlawfully denied promotions or transfers by the Company because of discrimination, pay lost due to removal from jobs in leaded areas, pay lost due to discriminatory layoffs, lost incentive or overtime pay, and by restoring appropriate seniority and fringe benefit credits to those unlawfully deprived of part or all of their seniority rights.

G. That the Court grant any other affirmative relief which may be necessary to place each of the individually-named plaintiffs and every other member of the class represented in the same position in which they would have been but for the unlawful employment practices of defendant Company, and to eradicate the effects of defendant Company's unlawful employment practices.

H. That the Court award the plaintiffs and the classes represented, costs and attorney fees, to be paid by the Company.

I. That the Court grant such other and further relief as the Court may deem appropriate.

[Signatures Omitted in Printing]

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

ANSWER

NOW COMES Defendant, Johnson Controls, Inc., by its attorneys, Stanley S. Jaspan, Renee L. Johnson and Susan R. Maisa, and as and for its Answer to the Complaint herein, admits, denies and alleges as follows:

1. With respect to Paragraph 1 of the Complaint, admits that Plainitffs are attempting to invoke the jurisdiction of this Court pursuant to certain federal statutes; denies that jurisdiction may be properly invoked in this instance pursuant to those statutes and denies each and every other allegation contained in Paragraph 1 of the Complaint.

2. Denies each and every allegation contained in Paragraph 2 of the Complaint.

3. Admits the allegations contained in Paragraph 3 of the Complaint.

4. With respect to Paragraph 4 of the Complaint, admits that Plaintiffs International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW, and its Local Union Nos. 12, 119, 509, 754, 1283, 1371 and 1516 filed a charge of discrimination with the EEOC alleging that Defendant has discriminated on the basis of sex through its fetal protection policy; denies that Defendant has committed any unlawful discrimination and denies each and every other allegation contained in Paragraph 4 of the Complaint.

5. Admits the allegations contained in Paragraph 5 of the Complaint, alleging in this respect that Defendant has committed no acts of unlawful discrimination.

6. Admits the allegations contained in Paragraph 6 of the Complaint.

7. With respect to Paragraph 7 of the Complaint, denies the allegations contained therein at least with respect to some of the named Plaintiffs.

8. With respect to Paragraph 8 of the Complaint, alleges that the proper statutory references are 42 U.S.C. § 2000e(d) and (e); admits the other allegations contained in Paragraph 8 of the Complaint.

9. Admits the allegations contained in Paragraph 9 of the Complaint, alleging in this respect that the Texas facility is located in Garland and not in Dallas.

10. Admits the allegations contained in Paragraph 10 of the Complaint.

11. With respect to Paragraph 11 of the Complaint, denies that UAW Local Union No. 1719 represents any bargaining units of Defendant; alleges that the proper statutory references are 42 U.S.C. § 2000e(d) and (e) and 42 U.S.C. § 2000e(a); alleges that the California facility is located in Fullerton and not in Pamona; alleges on information and belief that the address of Local Union No. 119 is 2922 Hillsdale Lane, Garland, Texas 75042, that the address of Local Union No. 509 is 7931 Seville Avenue, Huntington Park, California 90255, that the address of Local Union No. 1283 is 3421 Chateau Lane, Louisville, Kentucky 40219, and that the address of Local Union No. 1343 is 2414 Mamie, Texarkana, Texas 75501; admits the other allegations contained in Paragraph 11 of the Complaint.

12. With respect to Paragraph 12 of the Complaint, admits that Plaintiffs Lois Sweetman, Linda Burdick, Elsie Nason, Mary Estelle Schmitt, Shirley Jean Mackey

and Mary Craig are all employees of Defendant; denies each and every other allegation contained in Paragraph 12 of the Complaint.

13. Admits the allegations contained in Paragraph 13 of the Complaint.

14. With respect to Paragraph 14 of the Complaint, alleges that Plaintiff Linda Burdick is a resident of Bennington, Vermont, has been employed by Defendant since September 1978, and is currently on a medical leave of absence due to pregnancy; admits the other allegations contained in Paragraph 14 of the Complaint.

15. Admits the allegations contained in Paragraph 15 of the Complaint.

16. With respect to Paragraph 16 of the Complaint, alleges that Plaintiff Mary Estelle Schmitt is a resident of Hoosick Falls, New York; admits the other allegations contained in Paragraph 16 of the Complaint.

17. Admits the allegations contained in Paragraph 17 of the Complaint.

18. With respect to Paragraph 18 of the Complaint, alleges that Plaintiff Mary Craig is a resident of Middletown, Delaware; admits the other allegations contained in Paragraph 18 of the Complaint.

19. With respect to Paragraph 19 of the Complaint, admits that Anna May Penney is a citizen of the United States and a resident of Middletown, Delaware; denies knowledge or information sufficient to form a belief as to the truth of the allegation concerning her membership in UAW Local 1516; denies each and every other allegtion contained in Paragraph 19 of the Complaint; alleges that Anna May Penney was employed by Defendant at its Globe Battery Division Delaware plant from July 1971 to March 1984, at which time she voluntarily terminated her employment with Defendant.

20. With respect to Paragraph 20 of the Complaint, admits that Donald Penney is a citizen of the United States and a resident of Middletown, Delaware; denies knowledge or information sufficient to form a belief as to the truth of the allegation concerning his membership in UAW Local 1516; denies each and every other allegation contained in Paragraph 20 of the Complaint; alleges that Donald Penney was employed by Defendant at its Globe Battery Division Delaware plant from September 1981 to March 1984, at which time he voluntarily terminated his employment with Defendant.

21. With respect to Paragraph 21 of the Complaint, denies that Anna May Penney and Donald Penney are currently members of any bargaining unit of Defedant's employees; admits the other allegations contained in Paragraph 21 of the Complaint.

22 Admits the allegations contained in Paragraph 22 of the Complaint.

23. Admits the allegations contained in Paragraph 23 of the Complaint.

24. Denies each and every allegation contained in Paragraph 24 of the Complaint; alleges that Defendant is incorporated and exists under the laws of the State of Wisconsin.

25. With respect to Paragraph 25 of the Complaint, alleges that Defendant's corporate headquarters are located at 5757 North Green Bay Avenue, Glendale, Wisconsin 53209; denies each and every other allegation contained in Paragraph 25 of the Complaint.

26. Denies each and every allegation contained in Paragraph 26 of the Complaint.

27. Denies each and every allegation contained in Paragraph 27 of the Complaint.

28. Denies each and every allegation contained in Paragraph 28 of the Complaint.

29. With respect to Paragraph 29 of the Complaint, admits that no other individual has commenced a court action against Defendant concerning its Globe Battery Division fetal protection policy; denies each and every other allegation contained in Paragraph 29 of the Complaint.

30. Denies each and every allegation contained in Paragraph 30 of the Complaint.

31. With respect to Paragraph 31 of the Complaint, admits that Defendant maintains a fetal protection policy for its Globe Battery Division; denies each and every other allegation contained in Paragraph 31 of the Complaint.

32. Denies each and every allegation contained in Paragraph 32 of the Complaint.

33. Denies each and every allegation contained in Paragraph 33 of the Complaint.

34. Denies each and every allegation contained in Paragraph 34 of the Complaint.

35. Denies each and every allegation contained in Paragraph 35 of the Complaint.

36. Denies each and every allegation contained in Paragraph 36 of the Complaint.

37. Admits the allegations contained in Paragraph 37 of the Complaint.

38. With respect to Paragraph 38 of the Complaint, admits that the fetal protection policy includes lead exposure reduction procedures and defines women of childbearing capability as including all women except those whose inability to bear children is medically documented; denies each and every other allegation contained in Paragraph 38 of the Complaint.

39. With respect to Paragraph 39 of the Complaint, admits that since August 9, 1982, Defendant has imple-

mented and maintained a fetal protection policy at each of its Globe Battery Division facilities; denies each and every other allegation contained in Paragraph 39 of the Complaint.

40. Denies each and every allegation contained in Pargraph 40 of the Complaint.

41. Denies each and every allegation contained in Paragraph 41 of the Complaint.

42. Denies each and every allegation contained in Paragraph 42 and in each subpart of Paragraph 42 of the Complaint.

43. Denies each and every allegation contained in Paragraph 43 of the Complaint.

4. Denies each and every allegation contained in Paragraph 44 of the Complaint.

45. With respect to Paragraph 45 of the Complaint, admits that the percentage of female employees at Defendant's Globe Battery Division production facilities has not increased since the promulgation of the fetal protection policy; denies each and every other allegation contained in Paragraph 45 of the Complaint.

46. With respect to Paragraph 46 of the Complaint, admits that female employees capable of bearing children are discouraged from bidding for positions in high lead exposure jobs; denies each and every other allegation contained in Paragraph 46 of the Complaint.

47. Denies each and every allegation contained in Paragraph 47 of the Complaint.

48. Denies each and every allegation contained in Paragraph 48 of the Complaint.

49. Denies each and every allegation contained in Paragraph 49 of the Complaint.

50. Denies each and every allegation contained in Paragraph 50 of the Complaint.

51. Denies each and every allegation contained in Paragraph 51 of the Complaint.

52. Denies each and every allegation contained in Paragraph 52 of the Complaint.

53. With respect to Paragraph 53 of the Complaint, admits that under certain circumstances individual employees, male and female, may be given preferential treatment regarding placement in low lead exposure jobs pursuant to the terms of the applicable bargaining agreement; denies each and every other allegation contained in Paragraph 53 of the Complaint.

54. Denies each and every allegation contained in Paragraph 54 of the Complaint.

55. Denies each and every allegation contained in Paragraph 55 of the Complaint.

56. Admits the allegations contained in Paragraph 56 of the Complaint.

57. With respect to Paragraph 57 of the Complaint, admits that Ms. Sweetman would not have been transferred at the blood lead level at which she was transferred if she were not capable of bearing children; denies each and every other allegation contained in Paragraph 57 of the Complaint.

58. Admits the allegations contained in Paragraph 58 of the Complaint.

59. With respect to Paragraph 59 of the Complaint, admits that if Ms. Sweetman were not capable of bearing children she might have been allowed to return to a high lead exposure job when her blood lead levels decreased sufficiently; denies each and every other allegation contained in Paragraph 59 of the Complaint.

60. Admits the allegations contained in Paragraph 60 of the Complaint.

61. With respect to Paragraph 61 of the Complaint, admits that on January 24, 1984, the Delaware agency issued a preliminary determination finding reasonable cause to believe that Defendant had discriminated against Ms. Sweetman with respect to her sex; denies that there was any such discrimination and denies each and every other allegation contained in Paragraph 61 of the Complaint.

62. With respect to Paragraph 62 of the Complaint, admits that Plaintiff Linda Burdick was told that the fetal protection policy precluded her, as an individual capable of bearing children, from working in high lead exposure jobs; denies each and every other allegation contained in Paragraph 62 of the Complaint.

63. With respect to Paragraph 63 of the Complaint, admits that Ms. Burdick, as an individual capable of bearing children, was discouraged by Defendant from bidding on jobs with high lead exposure; denies each and every other allegation contained in Paragraph 63 of the Complaint.

64. Denies each and every allegation contained in Paragraph 64 of the Complaint.

65. Denies each and every allegation contained in Paragraph 65 of the Complaint.

66. With respect to Paragraph 66 of the Complaint, admits that Plaintiff Elsie Nason was transferred from her job as a side terminal welder because of her blood lead levels; denies each and every other allegation contained in Paragraph 66 of the Complaint.

67. With respect to Paragraph 67 of the Complaint, admits that Ms. Nason, who has not provided Defendant with medical documentation of her inability to bear children, is considered a woman of childbearing capability

as defined in Defendant's Fetal Protection Policy; admits the other allegation contained in Paragraph 67 of the Complaint.

68. With respect to Paragraph 68 of the Complaint, admits that if Ms. Nason were not capable of bearing children, she might not have been transferred from a high lead exposure job; denies each and every other allegation contained in Paragraph 68 of the Complaint.

69. Admits the allegations contained in Paragraph 69 of the Complaint.

70. With respect to Paragraph 70 of the Complaint, admits that Ms. Schmitt was told that the fetal protection policy precluded her, as an individual capable of bearing children, from working in high lead exposure jobs; denies each and every other allegation contained in Paragraph 70 of the Complaint.

71. With respect to Paragraph 71 of the Complaint, admits that the job Ms. Schmitt sought was given to a less senior male employee; denies each and every other allegation contained in Paragraph 71 of the Complaint.

72. With respect to Paragraph 72 of the Complaint, admits that Plaintiff Shirley Jean Mackey was transferred from her job as a C.O.S. loader to container punch/hot stamp operator; alleges that this transfer was due to a reduction in force and in accordance with her seniority; denies each and every other allegation contained in Paragraph 72 of the Complaint.

73. Denies each and every allegation contained in Paragraph 73 of the Complaint.

74. Denies each and every allegation contained in Paragraph 74 of the Complaint.

75. Denies each and every allegation contained in Paragraph 75 and in each subpart of Paragraph 75 of the Complaint.

76. Denies each and every allegation contained in Paragraph 76 of the Complaint.

77. Denies each and every allegation contained in Paragraph 77 and in each subpart of Paragraph 77 of the Complaint.

78. Denies each and every allegation contained in Paragraph 78 of the Complaint.

79. Denies each and every allegation contained in Paragraph 79 and in each subpart of Paragraph 79 of the Complaint.

80. Denies each and every allegation contained in Paragraph 80 and each subpart of Paragraph 80 of the Complaint.

81. Denies each and every allegation contained in Paragraph 81 of the Complaint.

82. Denies each and every allegation contained in Paragraph 82 of the Complaint.

83. Denies each and every allegation contained in Paragraph 83 of the Complaint.

84. With respect to Part VI of the Complaint, denies that Plaintiffs are entitled to any relief whatsoever.

ADDITIONAL DEFENSES

85. As and for its first separate and alternative defense, alleges that Plaintiffs fail to state a claim upon which relief can be granted.

86. As and for its second separate and alternative defense, alleges that this Court lacks jurisdiction over some of the claims contained in the Complaint because of the failure to file appropriate charges of employment discrimination with the Equal Employment Opportunity Commission within the time prescribed by the statute.

87. As and for its third separate and alternative defense, alleges that being an individual incapable of bearing children is a bona fide occupational qualification for employment in certain high lead exposure jobs in the Defendant's Globe Battery Division, pursuant to Sec. 703 (e) of Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-2(e).

88. As for its fourth separate and alternative defense, alleges that the Defendant's Globe Battery Division fetal protection policy is required by business necessity in order to protect the health and safety of the unborn children of women capable of bearing children from substantial and significant risk of harm from the exposure of such women to lead in certain jobs in the Defendant's Globe Battery Division facilities.

WHEREFORE, Defendant, Johnson Controls, Inc., prays that this action be dismissed in its entirety, that Plaintiffs be denied all relief prayed for in their Complaint, and that Defendant be discharged without delay, be awarded its costs expended herein, including reasonable attorneys' fees, and be granted such other and further relief to which it may be entitled.

Dated this 31st day of May, 1984

[Signatures Omitted in Printing]

[Affidavit of Service Omitted in Printing]

[EXCERPTS OF DEPOSITION OF E.A. ROSS]

(Horwitz Aff., Ex. A)

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* * * *

[67] Q. Now, other than office positions and non-office salaried positions, has the Battery Division hired women for any other positions?

A. Women of child-bearing capability?

Q. Yeah, at its manufacturing facilities since it adopted the Fetal Protection Policy.

A. That's what I was trying to answer before. In the Battery Plants, again, when you say manufacturing?

Q. Yes.

A. The best of my knowledge, the answer would be no, because the policy conditions haven't been met.

* * * *

[ROSS MEMORANDUM]

(Ross Depo., Ex. 8)

JOHNSON CONTROLS

Inter-Office Correspondence

Date August 16, 1982

Subject FETAL PROTECTION POLICY

From E. A. Ross

To GBD Plant Managers
GBD Plant Personnel Managers

The attached Fetal Protection Policy has been approved and is ready for implementation. Several points should be given your consideration:

1. Communication sequence should probably be Plant Staff, Local Union and the bulletin board (M. C. Zilis' policy statement as a permanent posting).
2. In the non-UAW battery plants (and Owosso and Toledo), we should attempt to get the Local Union "on board" through discussion. Pending written clarification of our right to prohibit transfers, the policy states that no fertile women will be hired. In all plants, our position is that we have the right to restrict transfers based upon company right to designate job, management rights clause, qualification aspect of transfer clause, etc.
3. From a "PR" point of view, we are *not* saying that we have discontinued hiring fertile females. We *are* saying that hiring is restricted as specified in the policy. Fertile females can and should be hired at times when policy conditions and restrictions are satisfied.
4. From an "AAP" and "EEO" point of view, paragraph "3" also applies. In addition, AAP's should

be reviewed in light of this policy. It is anticipated that committments regarding plant female hiring will be significantly lower in the future.

5. Please review your entire applicant flow procedures (including review of medical procedures with the Plant Nurse and Doctor). These, of course, vary from plant to plant. Perhaps the most practical procedure regarding applicants would be to ask your plant contact point (receptionist?) to inform female applicants that "we have no openings for women capable of bearing children at this time." Questions regarding fertility, the policy itself, etc. could then be referred to the Plant Nurse or Personnel.
6. Questions regarding sterilization will come from both employees and applicants. It's suggested that they be referred to the Nurse.
7. All of the above will be reviewed in greater detail during the Divisional part of our Personnel Managers' Meeting the week of October 25th. Meanwhile, feel free to direct questions to the undersigned, Mary Byrne or Jean Beaudoin.
8. In Texarkana and Florence, we are operating on the assumption that transfers into prohibited jobs would be minimal and can be prohibited under existing contracts. Accordingly, no limit should be put on the hiring of women of child bearing capabilities.

EAR:ss

cc: J. Beaudoin
M. Byrne
R. Rendl
W. Schmidt
J. Stuppia
R. Tippey
D. Van Horne
M. Zilis

[EEOC CHARGE]

(Horwitz Aff., Ex. A)

MS. LOIS A. SWEETMAN

* * * *

I. On January 10, 1983, I was transferred from my position as a C.O.S. Loader to the Formation Section.

II. I was told by James Fisher, that I was being moved to the Formation Section because my blood lead concentration reading was high and that I was being moved for the fetus protection plan.

III. I believe that I have been discriminated against on the basis of by sex, female, because:

1. Women who are in the child bearing age can not go back to the leaded section when their blood lead concentration is lower.
2. When men's blood lead concentration is low they can be moved back into their same position which is in a leaded area.

* * * *

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. C)

ELSIE NASON, MARY ESTELLE SCHMITT
and LINDA BURDICK

On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which it thereafter announced to its plants and to the unions representing workers at its plants. This policy was implemented without the consent of the unions representing the employees in the relevant bargaining units, and in violation of its collective bargaining agreements.

This policy on its face and as applied, discriminates on the basis of sex. It constitutes an overt sex-based classification, and it also has an adverse impact on the basis of sex. It particularly discriminates on the basis of sex as defined in the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964.

The fetal protection policy discriminates against both men and women on the basis of sex. This includes, but is not limited to, discrimination against women by requiring their removal from certain lead exposure jobs, resulting in discriminatory denial of employee opportunities, including promotion, transfer, hiring and placement on the basis of sex. In providing involuntary reproductive health hazard protection to women but not to men, the policy further discriminates on the basis of sex against men.

This policy violates Section 703(a)(1)(2) of Title VII, 42 U.S.C. Sections 2000e-2(a)(I) and

Specifically, the implementation of this policy at the Bennington, Vermont plant, discriminates against Elsie Nason, Mary Estelle Schmitt and Linda Burdick in the following ways:

In or about February of 1983, Elsie Nason was moved from her job as a site terminal welder because of the lead in the area, and because even though fifty years old and divorced, she is considered a fertile female. If Mrs. Nason were a male she would not have been transferred. Ms. Nason had been at the job of site terminal welder for the previous four years. The job move has meant a loss of both incentive pay and significant job satisfaction.

On or about June, 1983, Mary Estelle Schmitt was denied a job in Quality Control, which had just become available, and for which she had placed two advance bids in 1982. She was refused the job because she is a fertile female. She was told by the employer that she cannot work in a leaded area. The job was given to a male, with close to one and one-half years less seniority.

Linda Burdick has been discriminated against because her opportunity for advancement is far more limited than that of males. She has been informed that because of the existence of the "Fetal Protection Policy" she, as a fertile female, will not be allowed to work in a "leaded" area. She has been discouraged from bidding on jobs in leaded areas because of the existence of the Plan. If the Plan was not in effect, she would have bid on jobs in leaded areas as they became available.

This charge is filed by counsel on behalf of Elsie Nason, Mary Estelle Schmitt and Linda Burdick, as well as all others who may be similarly discriminated against by the implementation of the Globe Battery "Fetal Protection Policy."

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. F)

SHIRLEY JEAN MACKEY

* * * *

On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which it thereafter announced to its plants and to the unions representing workers at its plants. The policy was implemented without the consent of the unions representing the employees in the relevant bargaining units, and in violation of the collective bargaining agreements.

This policy, on its face and as applied, discriminates on the basis of sex. It constitutes an overt sex-based classification, and it also has an adverse impact on the basis of sex. It particularly discriminates on the basis of sex as defined in the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964.

The fetal protection policy discriminates against both men and women on the basis of sex. This includes, but is not limited to, discrimination against women by requiring their removal from certain lead exposure jobs, resulting in discriminatory denial of employment opportunities including promotion, transfer, hiring and placement on the basis of sex. In providing involuntary reproductive health hazard protection to women but not to men, the policy further discriminates on the basis of sex against men.

This policy violates Section 703(a)(1) and (2) of Title VII, 42 U.S.C. Sections 2000e-2(a)(I) and (2).

Specifically, the implementation of this policy at the Atlanta, Georgia plant discriminates against Shirley Jean Mackey by causing her removal from her job in a lead

exposure area because she is a fertile female. In or about April, 1983, Ms. Mackey was transferred from her job as a COS loader to a non-leaded area job, that of container punch operator. If Ms. Mackey were a male, she would not have been transferred.

This charge is filed by Counsel on behalf of Shirley Jean Mackey, as well as others who may be similarly discriminated against by the implementation of the Globe Battery "Fetal Protection Policy."

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. G)

MS. MARY CRAIG

* * * *

On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which thereafter announced to its plants, its employees, and to the unions representing workers at its plants. This policy was implemented without the consent of the unions representing the employees in the relevant bargaining units, and in violation of its collective bargaining agreements.

This policy, on its face and as applied, discriminates on the basis of sex. It constitutes an overt sex-based classification, and it also has an adverse impact on the basis of sex. It particularly discriminates on the basis of sex as defined in the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964.

The fetal protection policy discriminates against both men and women on the basis of sex. This includes, but is not limited to, discrimination against women by requiring their removal from certain lead exposure jobs, resulting in discriminatory denial of employment opportunities, including promotion, transfer, hiring and placement on the basis of sex, providing involuntary reproductive health hazard protection to women but not to men, the policy further discriminates on the basis of sex against men.

This policy violates Section 703(a)(1)(2) of Title VII, 42 U.S.C. Sections 2000e-2(a)(1) and (2).

In particular, the employer's fetal protection policy has discriminated on the basis of sex against charging party Mary Craig. The company's announcement of this policy

threatened her, unlike her fertile male co-workers, with loss of her desirable position working in a lead exposure area. Under the terms of the policy, Ms. Craig could only achieve job security if she were sterilized or otherwise became infertile. Her male co-workers were not required to prove infertility in order to be assured of job retention on these same exposure jobs.

The employer's imposition of infertility upon women but not men as a condition of secure employment discriminated against Ms. Craig, unlawfully coercing her into submitting to sterilization in order to be assured of her job. She elected to be sterilized on June 27, 1983.

This charge is filed on behalf of Ms. Craig and all others who may be similarly discriminated against by the employer because of its "fetal protection policy."

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. H)

MS. ANNA MAY PENNEY

* * * *

On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which it thereafter announced to its plants and to the unions representing workers at its plants. This policy was implemented without the consent of the unions representing the employees in the relevant bargaining units, and in violation of its collective bargaining agreements.

This policy, on its face and as applied, discriminates on the basis of sex. It constitutes an overt sex-based classification, and it also has an adverse impact on the basis of sex. It particularly discriminates on the basis of sex as defined in the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964.

The fetal protection policy discriminates against both men and women on the basis of sex. This includes, but is not limited to, discrimination against women by requiring their removal from certain lead exposure jobs, resulting in discriminatory denial of employment opportunities, including promotion, transfer, hiring and placement on the basis of sex. Providing involuntary reproductive health hazard protection to women but not to men, the policy further discriminates on the basis of sex against men.

This policy violates Section 703(a)(1)(2) of Title VII, 42 U.S.C. Sections 2000e-2(a)(1) and (2).

In particular, as implemented at the Middletown, Delaware plant, the employer's fetal protection policy discriminates on the basis of sex against Anna May Penney

by requiring her, because she is a fertile female, to wear a respirator when her blood lead level is lower than the blood lead level at which a male is required to wear one. Prior to the implementation of the fetal protection policy, the blood lead levels at which female and male workers were placed on and off respirators were the same.

This charge is filed by Counsel on behalf of Anna May Penney as well as all others who may be similarly discriminated against by the implementation of the Globe Battery fetal protection policy.

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. I)

DONALD PENNEY

* * * *

On March 6, 1984, Donald Penney and his wife Anna May Penney, both production workers at the Company's Globe Battery Division, Delaware plant, met with John Frey, the plant Personnel Manager, to discuss their requested Leaves of Absence. Mr. Penney had requested a three month leave of absence for the purpose of lowering his blood lead level to enable him to father a child. At the meeting Donald Penney was harassed and intimidated into quitting by Mr. Frey. The events of this March 6, 1984 meeting constitute a constructive discharge of Mr. Penney in violation of Sections 703(a) and 704(a) of Title VII, 42 U.S.C. § 2000e-2(a) and 3(a).

At the time of the meeting Mr. Penney and his wife, Ms. Penney, each filed an EEOC charge against the Company for discriminating against both men and women on the basis of sex through the Company's implementation of its "Fetal Protection Policy." The charges filed on January 1, 1984 and February 2, 1984 respectively, state, among other things, that the "Fetal Protection Policy" was a violation of Title VII, 42 U.S.C. Sections 2000e-2 (a)(1) and (2). Filing an EEOC discrimination charge is a protected form of opposition to employment discrimination.

Mr. Frey made the pending EEOC charges and potential lawsuit a major issue at the March 6, 1984 meeting. He informed Mr. Penney that he did not know why Mr. Penney would want a leave when Mr. Penney was suing the Company about the "Fetal Protection Policy" and that he, Mr. Frey, would recommend against

granting the leave. Throughout the meeting, Mr. Frey continually harassed and intimidated Mr. Penney and said that if Mr. and Mrs. Penney felt the way they did they should quit.

Mr. Frey's refusal to recommend that Mr. Penney be granted the requested leave, when other requested leaves have been granted, constitutes discrimination on the basis of sex, as well as retaliation for the Penneys' previous filing of EEOC charges. Mr. Frey's harassment and intimidation of Mr. Penney was intended to and had the effect of coercing him into quitting. It therefore constitutes a constructive discharge for the purpose of and having the effect of sex discrimination as well as retaliation for the Penney's previously filing EEOC charges.

The above-described discrimination was in part, if not entirely, in retaliation for the Penney's earlier filing of EEOC charges, as well as constituting sex discrimination in that Mr. Penney's request for a leave for procreative purposes would have been accommodated had he been a woman.

This charge is filed on behalf of Donald Penney by counsel.

* * * *

[EEOC CHARGE]

(Horwitz Aff., Ex. I)

MR. DONALD PENNEY

* * * *

On or after August 9, 1982, the Company propounded a "Fetal Protection Policy," which it thereafter announced to its plants, its employees, and to the unions representing workers at its plants. This policy was implemented without the consent of the unions representing the employees in the relevant bargaining units, and in violation of its collective bargaining agreements.

This policy, on its face and as applied, discriminates on the basis of sex. It constitutes an overt sex-based classification, and it also has an adverse impact on the basis of sex. It particularly discriminates on the basis of sex as defined in the Pregnancy Disability Act of 1978 amendment to Title VII of the Civil Rights Act of 1964.

The fetal protection policy discriminates against both men and women on the basis of sex. This includes, but is not limited to, discrimination against women by requiring their removal from certain lead exposure jobs, resulting in discriminatory denial of employment opportunities, including promotion, transfer, hiring and placement on the basis of sex. In providing involuntary reproductive health hazard protection to women but not to men, the policy further discriminates on the basis of sex against men.

This policy violates Section 703(a)(1)(2) of Title VII, 42 U.S.C. Sections 2000e-2(a)(1) and (2).

In particular, as implemented at the Middletown, Delaware plant, the employer's fetal protection policy discriminates on the basis of sex against Donald Penney in at least two respects. First, it denies him equally clean,

safe and free from hazard, terms and conditions of employment compared to women. Second, because the employer's policy unlawfully discriminates against women by requiring their removal from certain positions under certain circumstances, it also grants them preferential placement treatment. This results in disadvantageous treatment of male workers in placement, assignment, promotion and/or transfer to low lead exposure jobs, and unlawfully discriminates against these men on the basis of sex.

This charge is filed on behalf of Donald Penney, and all others who are similarly discriminated against on the basis of sex by the employer because of its "fetal protection policy."

* * * *

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

AFFIDAVIT OF EUNICE WILLIAMS

* * * *

3. On November 26 and November 27, 1984, I conducted a telephone survey of the UAW local unions which represent employees of the Battery Division of Johnson Controls, Inc. to determine the total number of production employees at each plant.

4. I determined that Johnson Controls, Inc. employs a total of approximately 2109 production employees at its Battery Division plant. 1834 of those employees are male and 275 are female.

* * * *

[Signatures Omitted in Printing]

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

AFFIDAVIT OF PAUL B. HAMMOND

STATE OF OHIO)
) ss.
COUNTY OF HAMILTON)

Paul B. Hammond, being first duly sworn, on oath, deposes and states as follows:

1. I am a Professor of Environmental Health at the University of Cincinnati. I have held this position since 1972. I received my degree in veterinary medicine in 1949 from Colorado State University and a doctorate in pharmacology from the University of Minnesota in 1955. Attached hereto and incorporated by reference as Exhibit A is my curriculum vitae which lists, among other things, my education and professional background, professional activities and memberships, as well as a bibliography of my professional publications.

2. As a professor at the University of Cincinnati my responsibilities include both teaching and research. In the teaching area, I am currently the Chairman of the Education Group Steering Committee, Department of Environmental Health. As Chairman I oversee the management and direction of several environmental health graduate programs. My current research responsibilities are in the area of the study of adverse effects of lead on children. In the past, I have done research into various aspects of lead toxicity. During my entire tenure at the

University of Cincinnati, I have been involved in the study of lead toxicity.

3. I am the director of a study that is currently being conducted in Cincinnati on the health effects of lead exposure on children. This study analyzes the subsequent mental development of children who have been exposed to lead both in utero and postnatally. The initial results of this ongoing study, which were released in the last year or so, establish that exposure of the fetus to maternal blood lead levels in excess of 12 micrograms per deciliter of whole blood creates a significant risk of low birth weight and a clear decrement in the subsequent mental development of the infant.

4. A similar study of the health effect caused by exposure of the fetus to lead is being conducted in Boston. The most recently published results of the Boston study, which were released in the last year or so, conclude that there is a clear decrement in the mental development of the infant at ages six months and twelve months when the mother has blood lead levels in excess of 10 micrograms during pregnancy. In both the Cincinnati and Boston studies, it was determined that the decreased mental development in the infants was caused by fetal exposure to lead, not postnatal exposure.

5. Based on these very recent studies, it is my opinion that it is medically unacceptable, from the point of view of the health of the fetus, for women to be exposed to lead which can result in blood lead levels in excess of 12 micrograms during pregnancy.

6. There is no clear evidence that exposure of the adult female to lead which causes blood levels of up to 50 micrograms will have any adverse effect on the performance of the female's reproductive organs.

7. I am not aware of any human studies which conclude that blood lead levels of up to, and even exceeding, 50 micrograms in the adult male will cause any demonstrable effect on the development of the fetus. Studies of the effect on the offspring of lead exposed male rats cannot be readily extrapolated to the human male, particularly as to the dose necessary to cause reproductive effects.

8. In 1975, Ioana Lancranjan published a study of the semen characteristics of men who were exposed to lead. The Lancranjan study concludes that at some level of lead exposure there is an effect on sperm morphology (shape). However, no conclusions can be reached from this study as to whether exposure of the adult male to lead will have any effect on the fetus. First, other studies have concluded that semen analysis is a very uncertain measure of reproductive function. Lancranjan admits in the study that it was merely a study of semen characteristics and was not to be taken as an indication of reproductive function.

Further, the measurement of the levels of lead in the blood of the men used in the study is highly suspect. There are basically three measures of lead absorption: lead in the blood, the Delta Amino Levulinic Acid (ALA) in the urine and lead in the urine. Lead in the urine and ALA in the urine have been correlated to blood lead levels. However, in the Lancranjan study, the reported blood lead levels did not correspond to the amount of lead and ALA that was found in the urine. Rather, the blood lead levels were too low for the level of the other two measurements of lead exposure. For example, for the group which reported a blood lead level of 75 micrograms per decaliter, I would have predicted the ALA to be only 19.2, instead of the 56.5 that was reported in the study. Conversely, if the 56.5 ALA measurement is correct, then I would predict that the blood lead levels would have been greater than 90 micrograms, rather than the 75 micrograms reported. Similarly, Lancranjan reports a urine lead of 385 for the 75 microgram blood lead group; however, based on a 385 urine lead, I would have predicted

a blood lead level of greater than 130 micrograms. The lead urine and the ALA reported for the other groups were also too high for the blood leads reported. It is my opinion that for some reason Lancranjan underestimated the true blood leads of the male workers in her study and, therefore, I believe no conclusion can be drawn from this study as to the blood lead levels at which there is an effect on the shape of the sperm.

9. This Affidavit is made and submitted in support of the Motion for Summary Judgment of Defendant Johnson Controls, Inc., in the above-entitled action.

Dated this 12th day of August, 1986.

[Signatures Omitted in Printing]

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

AFFIDAVIT OF JEAN BEAUDOIN

STATE OF MINNESOTA)
) ss.
COUNTY OF ST. LOUIS)

JEAN BEAUDOIN, being first duly sworn, on oath, deposes and states as follows:

1. I am the Manager of Health, Safety and Environmental Control for the Battery Division of Johnson Controls, Inc. ("the Company"). I have held this position since September 1978. I have been employed by the Company or its predecessor, Globe-Union, since 1972.

2. There are 17 plants in the Battery Division of the Company, 14 of which manufacture batteries. These plants produce a variety of automotive and specialty batteries. Lead is the principal active material used in the batteries. It is the principal ingredient of the paste which forms the plates of the batteries. Lead also forms the structure for the plates and all the conductive elements in the battery for transmitting current.

3. Plaintiffs, International Union, United Automobile, Aerospace and Agricultural Implement Workers of America and its respective locals are the collective bargaining representatives of the production employees at nine of the Battery Division plants. These nine plants are located in Fullerton, California; Garland, Texas; Louis-

ville, Kentucky; Middletown, Delaware; Owosso, Michigan; Bennington, Vermont; Atlanta, Georgia; Texarkana, Arkansas; and Holland, Ohio.

4. Attached hereto and incorporated by reference as Exhibit A is the Fetal Protection Policy that was implemented in 1982 and 1983 at all Battery Division facilities. It remains in effect today at all locations.

5. Attached hereto and incorporated by reference as Exhibit B is a true and exact copy of the transcript of selected portions of the testimony I gave on July 15 and July 16, 1985, in a proceeding conducted before the California Department of Fair Employment and Housing in connection with the implementation of the Fetal Protection Policy at the Battery Division plant located in Fullerton, California.

6. As discussed in my attached testimony (Exhibit B) at pages 118 to 121, the Company has instituted environmental engineering controls to reduce lead exposure at all its Battery Division plants. Since 1978 the Company has spent approximately fifteen million dollars on environmental engineering controls at its Battery Division plants, the vast majority of which are designed to reduce employee lead exposure.

7. Attached hereto and incorporated by reference as Exhibit C is a copy of the lead hygiene program currently in effect at all Battery Division plants. This is the Division's composite program for controlling lead exposure and lead absorption of employees. It identifies the various lead exposure reduction and monitoring programs in effect in the Battery Division. The provisions contained in Exhibit C are all currently in effect, with the exception that the goal of maintaining employee blood lead concentrations below 60 micrograms per 100 milliliters of blood was lowered to 50 micrograms and then to 40 micrograms, the current goal.

8. Attached hereto and incorporated by reference as Exhibit D is a copy of the biological monitoring and follow-up program currently in effect at all Battery Division plants for employees whose job duties expose them to lead.

9. Attached hereto and incorporated by reference as Exhibit E is a copy of the respirator program currently in effect at all Battery Division plants.

10. Attached hereto and incorporated by reference as Exhibit F is a copy of the medical surveillance program currently in effect at all Battery Division plants.

11. Attached hereto and incorporated by reference as Exhibit G is a copy of the program for periodic occupational evaluation for lead exposure currently in effect at all Battery Division plants.

12. Attached hereto and incorporated by reference as Exhibit H is a copy of the wash up and clothes changing program currently in effect at all Battery Division plants.

13. Attached hereto and incorporated by reference as Exhibit I is a copy of the program for work clothing and footwear currently in effect at all Battery Division plants.

14. The lead exposure reduction programs that are attached hereto as Exhibits C through I are described in my attached testimony (Exhibit B) at pages 125 to 133.

15. Attached hereto and incorporated by reference as Exhibit J is a copy of the policy guidelines for employment in lead exposure of women capable of bearing children that was in effect in the Battery Division from 1977 until the implementation of the Fetal Protection Policy in 1982 and 1983.

16. Attached hereto and incorporated by reference as Exhibit K is a chart which lists some of the pregnancies that occurred at the Battery Division plants during the

last 4 years that the voluntary fetal protection program (Exhibit J) was in effect in the Battery Division. This chart is described as Exhibit I in my attached testimony (Exhibit B) at pages 153 to 154.

17. The Company considered alternative methods to protect the health of the fetus from exposure to lead prior to adopting the Fetal Protection Policy. These alternatives were rejected because they did not adequately protect the health of the unborn children of the Company's workers. For example, as discussed above, the Company adopted an educational and counseling program (Exhibit J) for those females capable of bearing children, urging them to avoid those work areas where their blood lead might exceed 30 micrograms. This voluntary program was inadequate because, as demonstrated in attached Exhibit K, significant numbers of women became pregnant while having blood levels in excess of 30 micrograms. Further, the Company has attempted to develop an alternative to lead acid batteries in order to totally eliminate ~~lead~~ exposure; however, these attempts have been completely unsuccessful to date. We have continud to study, develop, and implement engineering controls to reduce the lead exposure and blood lead levels of all employees. However, there are not presently available engineering controls that will reduce lead exposure in the Battery Division plants to a level which will assure that all employees will have blood lead levels below 30 micrograms.

18. Attached hereto and incorporated by reference as Exhibit L is a pie chart which shows the profile of blood lead distributions in the Battery Division plants in April 1982 as compared to April 1985.

19. Attached hereto and incorporated by reference as Exhibit M is a tabular chart of the blood lead distributions in the Battery Division plants at the end of April for the years 1982, 1983, 1984 and 1985.

21. This Affidavit is based upon my own personal knowledge and my review of Company records and is submitted in support of the Motion for Summary Judgment of Defendant Johnson Controls, Inc., in the above-entitled action.

Dated this 12th day of August, 1986.

[Signatures Omitted in Printing]

[FETAL PROTECTION POLICY]

(Beaudoin Aff., Ex. A)

JOHNSON CONTROLS

STANDARD PROCEDURE

Division BATTERY

Section HSECD

Date Effective 11-01-82

Date Revised 07-21-83

Bulletin No. 3-954-01

Endorsed By VP MFG., Dir. Personnel

Distribution 3X-39 & SPECIAL

Subject FETAL PROTECTION PROGRAM
IMPLEMENTATION PROCEDURE

I. *Scope*

A. This standard procedure establishes the procedure for implementing the Fetal Protection Policy (See Exhibit A in the Branch Plants and at Glendale. It is applicable to women of childbearing capability.

B. These practices do not apply to women who have medical confirmation of their inability to bear children, and is in no way intended to support or encourage women of childbearing capability to seek to change this status. Employees are strongly advised against any such action.

II. *STANDARD PRACTICES*

A. Definitions

The following terms are defined for the purpose of this document:

1. *Women of childbearing capability*—All women except those whose inability to bear children is medically documented.

2. *Basic Action Plan*—Implementation of full shift respirator wear requirement and, where feasible, end of shift showering.

3. *"Acceptable" work station*—A work station where the blood lead readings of the incumbents over the past year are < 30 ug% and air-lead ratings are < 30 ug/m^3. Note however, that an incumbent employee covered by this policy need not be transferred if she maintains a blood-lead reading < 30 ug% in an air exposure ≥ 30 ug/m^3.

4. *Medical Removal Protection (MRP) Benefits*—refer to SPB 3-953-04, V,K,l. for details. MRP benefits will continue until such time as the employee:

   a. no longer has childbearing capability and fails to take advantage of a bid opportunity for a job for which she has sufficient seniority and is otherwise qualified, or

   b. fails to take advantage of a bid opportunity for an "acceptable" job in the same or higher classification for which she has has sufficient seniority and is otherwise qualified.

(Note: The 18 month limitation does not apply to employees transferred under this procedure.)

All removals from lead exposure under this program are considered to be permanent, and not temporary moves.

B. References

SPB 1-950-20 Medical Surveillance Program
SPB 3-950-21 Pre-Employment Examinations
SPB 3-953-04 Biological Monitoring Program
SPB 3-953-11 Respirator Program

C. Responsibilities

1. The Plant Manager shall be responsible for the implementation of this procedure through the Personnel Manager.

2. The Manager of Personnel Administration shall be responsible for review of personnel procedures and forms and coordination of these practices with EEOC/AAP policies.

3. The Manager of Health, Safety & Environmental Control shall be responsible for establishment and review of this procedure and for auditing compliance thereto.

D. New Hires

Women of childbearing capability will only be hired:

REVISED

1. In jobs where, within the past year, no blood-lead sample result has been ≥ 30 ug% and no air-lead sample result has been ≥ 30 ug/m^3.

2. In jobs from which transfers into jobs described in "1" can be prohibited.

E. Existing Employees

REVISED

An existing employee capable of bearing children shall be placed only in a job where, within the past year, no blood-lead result of any of the incumbents (transferees excluded) has been ≥ 30 ug% and no incumbent's air-lead exposure has been ≥ 30 ug/m^3, except that an incumbent employee covered by this policy need not be transferred if she maintains a blood-lead reading < 30 ug% in an air exposure ≥ 30 ug/m^3.

F. Biological Surveillance Program

1. All women of childbearing capability shall be counselled as to the effects of lead and the importance of personal hygiene and good work practices at the time each blood-lead sample is executed.

2. Biological monitoring frequency

Blood lead < 20 ug%—sample every 3 months
Blood lead 20-29 ug%—sample every 2 months with ZPP in the interval between (battery plants only)

Blood lead ≥ 30%—sample monthly

G. Placement Practices

1. Individual with blood leads ≥ 40 ug% (confirmed)

   a. Implement basic action plan.

   b. Transfer as soon as possible to an "acceptable" work station. Implement Medical Removal Protection benefits.

2. Individual with blood leads 35-39 ug%

   a. Basic action plan.

b. After two readings in this range, encourage voluntary transfer. Restrict exposure to 40 hours/week in air-lead levels $\geq$ 30 ug/m^3.

c. After *four* readings in this range transfer as in G.1.b. above.

3. Individual with blood-leads 30-34 ug%

a. Basic action plan.

b. After *three* readings in this range, encourage voluntary transfer. Institute overtime restriction as in G.2.b. above.

Give priority to transfer to an acceptable opening in the same job class.

c. After *six* readings in this range, transfer as in G.1.b above.

NOTE: Actions at steps G.2 and G.3 are triggered by the *total* number of consecutive readings in the 30-39 ug% range.

4. If an employee's blood-lead rises to $\geq$ 30 ug% institute steps as outlined in G.1, 2, and 3 above, depending on blood-lead level.

H. Employee Training

Any employee covered by this procedure, whose blood-lead level is $\geq$ 15 ug%, shall participate in an annual lead education program with emphasis on health effects of lead absorption.

Special Distribution

Plant Occupational Health Nurses

Plant Physicians

EXHIBIT A

Johnson Controls, Inc.
5757 N. Green Bay Avenue
Post Office Box 591
Milwaukee, WI 53201
Tel. 414/228 1200

Milton C. Zilis
Vice President & General Manager

Globe Battery Division

August 9, 1982

FETAL PROTECTION POLICY

We have over the years developed policies to protect the health of our employees whenever the nature of their duties may expose them to a health hazard and to prevent members of their families from being exposed to a health hazard because of their employment with Globe Battery Division.

Medical research has shown that a woman's exposure to lead can cause ill effects on the health of her unborn child because the lead absorbed in the mother's blood as the result of this exposure can cross the placenta and mix with the child's blood. This has been acknowledged by the Occupational Safety and Health Administration.

Medical research also shows that a risk to the unborn child's health is present at a much lower blood-lead level than an adult. The ill effects to the unborn child can occur during the early stages of pregnancy, before the mother is aware that she is pregnant, and can continue throughout the pregnancy.

Because of this, it is the Division's policy that women who are pregnant or who are capable of bearing children will not be placed into jobs involving lead exposure or

which could expose them to lead through the exercise of job bidding, bumping, transfer or promotion rights.

This policy is intended to reduce or eliminate the possible unhealthy effects of lead on the unborn children of pregnant employees and applicants. It does not apply to those women who have medical confirmation that they cannot bear children. However, the policy is in no way intended to support or encourage women of childbearing capability to seek to change this status. Employees are strongly advised against any such action.

/s/ M. C. Zilis
M. C. ZILIS

[EXCERPTS OF BEAUDOIN TESTIMONY]

(Beaudoin Aff., Ex. B)

* * * *

[118] Q How does the company protect against excessive exposure of employees to lead?

A We have a comprehensive program in that regard. Foremost, of course, is employee education, training, counseling. We rely very heavily on engineering controls and have since long before I joined the company. We utilize work practices, programs with the employees, housekeeping programs, respiratory protection, work clothing and equipment and shoes, and an ancillary function of this is to keep all the lead that an employee may contact in the plant in the plant, not to allow it to go home.

These programs are, say, monitored, if you will, through our air sampling program which tends to document the employees exposures, the individual exposures that an employee would experience during a normal working day. Then this is all buttressed by our medical surveillance programs and our biological monitoring program.

* * * *

[122] Q What do you mean by personal hygiene practices?

[123] A Well, lead can be inhaled in the form of dust or fume. It can also be ingested through transference by contact. And employees can get lead on their hands, they can get it under their finger nails. They can easily transfer this to their face through normal habits that are perfectly innocuous in every day life, brushing perspiration of the brow, scratching an itchy noise, (sic) stifling a cough or a yawn, blowing one's nose. These are all things that must be done with care and it is important that people do this and it's a behavioral practice that one has to learn.

Q You mentioned air sampling, what does air sampling do; what does it measure?

A All right. Air sampling is done with a personal sampling pump that the individual wears. The air is drawn into the pump through a filtered cassette that's positioned on the shoulder or lapel of the employee and, as such, it's drawing in air that's in the approximate breathing zone of the person. Sampling for monitoring of exposures is normally done for full shifts and this would include whatever the employee's exposed to in a regular job, the clean up, if the employee is involved in doing special duties that day because perhaps the line on which he's normally working or the operation he's normally working is down for some reason, you monitor that because that's what that employee's exposure is.

Q What do you measure, what are you measuring in taking the air sample?

A You're collecting lead on a filter, you're drawing, in essence, a known amount of air through that filter so you're [124] collecting a known amount of lead from a known amount of air. So you end up with a calculatable concentration of lead in air and you know the amount of air that you're drawing through the pump because you calibrate the pump at the start of the shift and again at the end of the shift.

Q And when reference is made to air leads, is that what you get as a result of the sampling?

A When you talk about the air leads, you're talking about the lead in the air, concentrations that are measured in the process.

Q Will two employees exposed to the same air leads have the same blood leads or same amount of absorption of the lead?

A Not necessarily.

Q Why is that?

A Well, I think no two of us are precisely the same biologically. Secondly, there are two components, two avenues or two pathways for moving lead from the ambient into the body: one is inhalation and the other is ingestion or personal hygiene and contact.

So in the early days when air lead levels were very very high, airborne exposure was the overwhelming route of lead that was entering the body. As exposures have been controlled increasingly more tightly as they are in today's environment in a manufacturing plant, in our plants at least, then the components that can enter the body through ingestion, through lack of less than good personal hygiene can become very significant.

[125] And so it's impossible to precisely correlate air leads to blood leads. Certainly, as air leads increase, blood leads will rise, but you cannot correlate it precisely. A further complicator would be respirators.

If you use respirators, you are in effect screening out a great deal of the airborne contaminant that could be inhaled.

Q Would two employees who work in the same work station have the same air leads necessarily?

A No. Again, you're dealing with work practices and the effect of individual work practices will be to give rise to variability. I think workers can be consistent, but if you were to sample the same individual day after day and he's involved in the job where he's handling product, you will see that the exposure is going to have some variability from day-to-day and much more so if you go from employee to employee.

Q I ask that you look at what I believe has already been introduced as Department Exhibit 7. Can you identify that document, please?

A It is Johnson Controls battery division standard procedure bulletin entitled "Biological Monitoring Program for Battery Division Employees".

Q And generally what does it provide?

A It establishes the program for biological monitoring and follow-up for employees who have lead exposure.

Q What is biological monitoring; what do you mean by that phrase?

A As we—as we're using it here, biological [126] monitoring would refer to blood samples which are ana-

lyzed for blood lead content, lead content, I should say, which is reported as blood leads, also analyzed for hemoglobin or analyzed either for zinc protoporphyrin or free eryrthrocytes, F.E.P. It may have been referred to earlier as F.P.P. I'm not certain.

Q What are the purposes of these various biological monitoring tests?

A The blood lead test, blood lead level basically is a measure of the amount of lead that is circulating in an individual's blood stream. The other tests are more nearly measures of the effect lead is having on the body.

Q What determines how often an individual is tested?

A Our biological monitoring frequency is determined by blood lead levels, or Z.P.P. levels, the particular area worked in, whether the employee is a new employee in lead exposure or not, whether the employee is a woman who is capable of bearing children. There are a great many factors that will influence that frequency.

Q Who decides or on what conditions is an individual removed or restricted in placement because of lead exposure?

A There are really two mechanisms by which that can happen. Number one, the plant physician in reviewing the monitoring results of the employee, from the employee, both air leads and the biologicals and in perhaps in talking with the employee and examining the employee, may reach a conclusion that that employee should be removed from exposure. And it's a medical determination. [127] The other is via the numerical criteria in our policy which are blood lead criteria which would be either a 60 micrograms percent blood lead reconfirmed or running six-month average of blood leads in excess of 50 or at or above 50.

* * * * *

[128] Q I'll show you what's been marked as Respondent's Exhibit A and ask you to identify that document?

A This is labeled a Globe Union, Inc. standard procedure bulletin. It is 1-957-03. It's entitled "Lead Hygiene Program" and this is basically an umbrella bulletin, if you will, that covers the lead exposure control programs.

There's several programs that we have in place; air sampling, respirators, wash up and clothes changing, work clothing, housekeeping, training, engineering controls. It's meant to be basically an overall bulletin that identifies these different programs.

Q I notice the date last revised is June 15, '79; is it still in effect?

[129] A Yes, it is.

Q With respect to the Policy A, is there any change there?

A. That's a good point. The Item A-3, this bulletin says that it is our policy to maintain our employees blood lead concentration between 60 micrograms percent and that was our policy at that time which was at the very outset or approximately at the time the blood standard was issued.

Our policy today is to control below 40 and beyond that, ultimately to get as low as we possibly can.

* * * *

[131] Q Can you identify what's been marked as Respondent's Exhibit C?

A This is a Globe Union standard procedure bulletin number 1-950-22. It's entitled "Periodic Occupational Medical [132] Evaluation".

Q And what is this about?

A It describes and governs the periodic examinations and evaluations that a plant physician would make of lead exposed employees.

Q What is its purpose?

A Its purpose is to—it's part of our overall employee protection. It's intended and this is the step where you would be examining the employee to ascertain that there is no impairment, no impairment of health due to lead or that if there is, to determine what it might be and the extent to which it may exist and, if necessary, to determine what corrective action should be taken.

* * * *

[140] Q Prior to any OSHA standards in that regard, did the company pursuant to these policies, restrict placement of employees and take other such action?

A The company had comprehensive lead exposure control programs and medical surveillance programs and biological monitoring programs in effect well in advance of the lead standard.

In terms of engineering controls, there were very [141] extensive ventilation controls in place when I joined the company in 1972. And there's been a great deal of refinement and augmenting that has taken place since, but that effort goes back well beyond me.

The biological monitoring program and medical surveillance did contain provisions relating to lead transfers. We had our own transfer triggers which were in effect prior to the lead standard and when the lead standard first came into effect, we had triggers which were lower than the lead standard.

Basically, the programs were more protective than what was required by the regulation. And we did have both the dual mechanism of the blood lead trigger as well as physician's medical judgment.

Q What are medical removal protection benefits?

A Medical removal protection benefits are basically the payment—if an employee is removed from a job which entails lead exposure and the person is removed either because of a physician's medical judgment or because the blood lead trigger is reached, the employee is compensated at the average earnings of the job he was removed from, if necessary.

And by way of explanation, a great many of our production jobs are incentive jobs so that as the productivity of the individual or of the group of which he is a member increases, so do the earnings. When an individual is transferred away from a job, of course, if it's a non-incentive job, a straight-time rate, fine. If the job to which he goes has the same rate or higher, there are no benefits paid. If the rate is lower, then the individual's

right is maintained at the [142] rate from which the person was removed. With an incentive job because the earnings day-to-day can be different depending on productivity, we compute an average straight time hourly earnings of while the individual was in the job and that becomes the basis against or the benchmark against which the earnings after the transfer are compared. If the earnings after the transfer are greater, no benefits are paid. If the earnings are less, then the individual is compensated up to that level.

Q Did the company provide for medical removal protection benefits prior to the OSHA standard making any mention of them?

A Yes.

* * * *

[143] Q Do any of the company's current policies exceed the OSHA requirements?

A Yes.

Q Which policies as examples?

A As examples, number one, our biological monitoring policy monitors a greater frequency than that required by the lead standard.

Number two, we prescribe follow-up corrective actions whenever we see certain indications. That is not contained in the lead standard. We have actually implemented engineering controls in instances where air leads themselves would not have required it, but where we felt there was a significant risk to employees.

We have, let's see, our medical surveillance program has aspects of it which are more comprehensive than what is required by the standard.

I believe our training programs go beyond the letter of the regulation. We provide work clothing to people to [144] whom we are not required to provide it under the lead standard. We provide greater change frequency than is required by the standard. We provide and require showering and hand washing of individuals where it is not required by the standard.

If I thought further, there may be others as well.

* * * *

[151] Q Mr. Beaudoin, will you look at Department's Exhibit 5, please. Can you identify that document?

A It is a Johnson Control Standard Battery Division Standard Procedure Bulletin Number 3-954-01 entitled "Fetal Protection Program Implementation Procedure".

Q Is that policy currently in effect?

A Yes, it is.

Q How did that policy come about?

A We have over time been monitoring medical literature as relates to lead and this includes fetal and reproductive effects. Our medical consultant and some of our plant physicians have been recommending to us that we implement a policy in that the risk to the fetus who might be present in the work place as carried by the mother was too great a risk medically.

And we had had a voluntary policy or program in effect and the results of that program indicated that we were seeing, number one, a high number of women who were capable of bearing children with high blood leads and, even more to the point, we were seeing a substantial number of pregnancies where the blood leads of the mother were well in excess of 30. Based upon that, we felt it was necessary to take this type of an action.

* * * *

[152] A This is the guideline defining the voluntary program that was in effect.

Q What was the date of the guidelines?

A June 9th, 1977.

Q What was the purpose of those guidelines?

A The purpose of the guidelines was to reduce the risk to children our women employees would bear by a thorough effort of counseling, educating them to the risks that they were undertaking by working in lead exposure with the hope that as they came to understand and recognize what the magnitude of the risk was, that they would remove themselves from that exposure.

And as a means of trying to emphasize the gravity, the importance have this point, as we had these discussions with them, as our medical people had these discussions, we asked them to sign the statement that they acknowledged they understood these risks and we tried to do this in a high profile manner with the employee as a means of emphasizing the gravity of the situation.

* * * *

[153] Q Why did the company cease using this voluntary policy on fetal protection?

A Well, as I indicated earlier, we were seeing significant numbers of women who were fertile having high blood leads and even more serious than that, they became pregnant with these high blood leads.

* * * *

[155] Q How does this policy work; what is the purpose in terms of specifically?

A The policy basically determines or sets up the mechanism for determining whether an employee or an applicant is capable of bearing children and then takes steps—takes a step with the employees of assuring that they are in positions where their blood leads and the air leads do not exceed 30 micrograms per cubic meter of air, especially the blood leads, and provides the programs that are necessary to assure this occurs.

Q Why do you want that to occur?

A In order to be able to protect any fetus the woman might conceive and carry. The fetus' exposure is from the mother's—the lead in the mother's body, specifically, and most actively the lead in the blood and the mother's blood lead is not strictly a function of her current exposure, but also can be a function of her previous exposure.

[156] Q What happened under this policy to women who were in jobs that became unacceptable?

A As the policy was implemented to minimize the impact it would have and the disruptive impact it would

have on our employees and where employees were working in positions where they had successfully controlled their own blood leads, in other words, they had the mix of, proper mix of personal hygiene practices and work practices that would allow them and they had demonstrated this capability to control their blood leads below 30 consistently, we allowed them to stay in this position.

Also, that's a bid of a phase-in period there where if an individual had blood leads that were slightly above 30, she had the opportunity and we provided her with a variety of assistance, methods of assistance to help her to get her blood lead down below 30 within a specified period of time to stay on-the-job.

Once that occurred, as long as blood leads could be maintained within the guidelines of the policy, they could stay there.

Q What about the woman whose blood leads remained above 30?

A Women whose blood leads remained above 30 were transferred according to the policy into jobs that would be defined as acceptable positions; that is jobs for which there were no air leads or blood leads indigenous to the job above 30 in the past year. And by indigenous to the job, I would mean the lead absorption or the exposure results from that particular job.

[157] So you would, if someone transferred into one of those jobs from another job in the plant and had a high blood lead as they made the move, we would exclude that from the consideration because that high blood lead was not developed on that job. Correspondingly, although the situation has not yet arisen to my knowledge, if we had knowledge of an individual who happened to have a hobby, perhaps working with stained glass, perhaps heavily involved in target shooting at rifle ranges or pistol ranges, perhaps moonlighting as a plumber somewhere where they could get lead exposure other than in our employ, that's something we would have to consider too as to whether that particular—those blood lead readings would be a disqualifier for someone else in that position.

And the same thing would apply to an air leads. If an employee who normally works on that job happened to work on another job on that given day and get air sampled on that day, the position we're considering would not be penalized by the air leads incurred there.

Q For the woman who is transferred to a lower paying job, what happened to her wages?

A Any woman transferred because of this policy would receive medical removal protection benefits.

Q What does that mean?

A As we defined them yesterday, that would be compensation to assure that her earnings would not be diminished by that move.

Q Under the policy of the medical removal protection benefits, are they limited to the 18 months provided for in the [158] OSHA standard?

A No.

Q What time period does it follow?

A These benefits would apply until any one of a couple of things could happen. Number one, until the woman became infertile and was no longer covered by the policy and also had the opportunity to bid onto another job that would be compensating her at a level equal to or higher than that benchmark.

Secondly, it could occur that a woman who while covered by the policy would be able to successfully bid onto another acceptable job that would have a rate of pay that would be equal to or greater than the benchmark of the M.R.P. benefits.

Q You referred to women on the job being allowed to stay there if their blood leads were below 30 even though the job was unacceptable. Were other women covered by the policy, those women capable of bearing children permitted to first enter those jobs?

A Where the air leads were above—

Q The blood lead of other individuals were above?
A No.
Q Why not?
A Well, several things: Number one, as we discussed earlier, in a great many of our jobs the individual work practices of the employee in handling the product which is the dust producing contaminant are a key factor in the overall exposure that they receive. And this is, therefore, going to [159] vary from individual to individual.

Moreover, we see that when an employee, either a new employee is put into a job or an employee transfers into a new job, that is usually the time of highest—that initial period is usually the time of highest exposure and very often the highest blood leads because their exposure goes up until they become familiar with and master the individual work practices that pertain to that job. And that higher exposure usually translates into higher blood leads as well.

* * * *

[163] Q Why doesn't the company allow the new employees to be hired into acceptable jobs or current employees to transfer in until their blood leads rise to 30 micrograms?

A Well, in a sense that's a form of human experimentation. You're taking a risk that, if you did that, you'd be gambling that the woman might not become pregnant and if she did, there wouldn't be enough lead absorption in the mother to create a problem.

It's unacceptable because, first of all, you can't monitor blood leads daily or even weekly. It's an invasive technique of sampling in a vein. It's not good medical practice to do that any more often than is absolutely necessary and trying to do it on a semi-continuous basis is unsound. And it has the potential to seriously damage the woman's veins.

Secondly, as we mentioned earlier, because of work practices, the potential for the greatest exposure is right

at the outset while the employee is learning the proper work practices. So you'd be allowing the individual to work at the time of greatest risk. And if the individual remained in that position for a while, there's going to be a development of some body burden of lead.

Q Why not limit the policy to those women who are planning pregnancies?

[164] A A variety of reasons for that. Number one, birth control devices are not a hundred percent effective. Secondly, the best of intentions and resolve can sometimes be forgotten under the pressure or the circumstances of a given incident or moment and there's too great a risk, there's too great a frequency of unplanned pregnancies, which I think we all know, and maybe it's happened to us or it happens to our friends.

Q The policy, as I understand it, defines an unacceptable work station not only on the basis of blood leads but on the basis of air leads as well; why is that?

A Number one, the employee's exposure is variable from employee to employee because so great a contribution is dependant upon the employee's own practices.

Secondly, individual biological response to that exposure, the amount of lead one absorbs from a given exposure is going to be different. And whereas, some people might respond in a given job very little, others may respond a great deal.

Q The policy uses a single air sample or single blood sample as a basis for determining that a job is unacceptable; why is that done instead of the use of a mean or median?

A Well, a mean or median implies a range and if you had a random distribution, everyone would have an opportunity for a random high reading and random low readings, but practically, what usually happens is your most experienced people will usually have the best work practices and, therefore, the lowest exposures and the lowest blood leads. You're newest people would usually be at the high end of that range.

[165] So if you picked a job where the median or mean was at a certain level, chances are your newest people would be the ones that would exceed the number on the upper end of the range and that's basically unacceptable. We have to make sure that we are controlling that exposure and that absorption to below the levels that we have indication are safe.

* * * *

[167] Q Did Johnson Controls consider alternatives to addressing the problems of fetal exposure other than the existing current fetal protection policy?

A Yes.

Q What were the alternatives and why were they rejected?

A Number one, the voluntary guidelines that we had in effect for five plus years which, as I mentioned earlier, were not effective in controlling the blood leads of women who were capable of bearing children below 30, and even more seriously, they were not successful in preventing pregnancies with blood leads above 30.

We've also, as I mentioned yesterday, have been seeking for a period of time to try to develop alternate batteries to low lead acid batteries and that has not been successful.

As we were developing this particular policy, we looked at how long we thought it would take us to be able to engineer lead exposures down to the 30 air and to the level that [168] we could be assured that blood leads would be below 30 in our plants and the conclusion on that was that there was so much that we did not know yet in how to achieve this, that it would probably be approximately a decade at least before we could achieve exposures that were 30 air or below throughout our plants.

We are continuing to develop engineering controls and we just this summer, as an example, have completed the installation of a major make-up air system in the element assembly and intercell welding departments here in the

Fullerton plants and this type of practice is an ongoing one for us.

We continue to look at options that may be available and certainly are open and will continue to be open to possible alternatives and suggestions that may offer an opportunity to modify our present program.

Q In terms of the engineering controls, are those controls to lower the levels of lead in the air available for purchase and how are they developed?

A Well, typically, the concept of what you're trying to do of reducing an exposure at a given work station in a given operation is something that you have to develop yourself. You've got to document what the sources of exposure are, how they arise and then try to determine how they can be controlled. And from that determination, then you have to try to develop what equipment or hardware, what designs, mechanical designs will work.

The individual pieces that go into a system, some of them are custom designed and fabricated and some may be [169] purchased on the outside; such as fans, bag houses or other dust collectors, make-up air units. These are basically standard items that can be purchased.

But the most critical component of the effectiveness, that speaks to the effectiveness of these systems, is the design of the hooding or the duct work, the tamping stands, the innovative design on material handling systems. Sometimes in order to be able to make a given change to control exposure or to further reduce it, you may end up having to make up modifications to the process to allow you to do that and it's a time consuming process. It's an evolutionary process. It's not something that you typically can move in one bold stroke and completely solve all of the exposure problems in a given department. You take a step. You analyze the progress you've made with that step. You then determine what your remaining problems or sources of exposure are, determine how to best control those and proceed to the next level.

And as we learn a new step and try it at one of our plants and if it proves successful, we then proceed to implement it in the other plants. And when you're dealing with 14 plants, there's a process here. You make advances, you know, some advances have been made in just about every plant where something new has been developed and it's been a case of once that proves convenient, you extrapolate it and adapt it and design it to put in the other plants.

Q Is the technical know-how currently available to reduce the air leads and blood leads at all plants at all work stations below 30?

[170] A Do we know how today to do it, no. It's something that we still have to study to learn. It's technology that has to be developed.

Q What measures, if any, is the company taking with respect to the medical literature and the scientific evidence in this area?

A This is something which is a matter of ongoing review. We stay abreast of the literature as it develops through our trade association. We contribute funds toward the support of research, primary university research, that is conducted in various environmental health areas including reproductive effects.

As a matter of fact, we had offered to make available our Fullerton plant here, the work force in our Fullerton plant, subject to the individual's willingness to participate in a study, on the effects of lead exposure on male reproductive effects. This was a study that was developed and under the direction of our plant physician who is a professor—or I think it's a professor—in the medical school at University of California, Irvine, Dr. Dwight Culver.

Unfortunately, that particular study did not get done because the government grants that were sought for the study did not come through. But this is something that we continue to be open to and to be willing to participate in. And, for instance, Dr. Blejer yesterday mentioned the Cooper Gaffey study which was, that was a mortality

study but the populations from two of our plants were included in that study as well.

* * * *

[179] Q Do you have any employees that are required to wear respirators full-time in the plant?

A Do we have employees who wear respirators full-time in the plants, yes.

Q Are all of their blood leads below 30?

A No.

* * * *

[LEAD HYGIENE PROGRAM]
(Beaudoin Aff., Ex. C)

GLOBE-UNION INC.

STANDARD PROCEDURE

Division CORPORATE
Section CORP. RELATIONS
Date Effective 11-23-73
Date Revised 06-15-79
Bulletin No. 1-953-03
Endorsed by V.P., CORPORATE RELATIONS,
V.P. BATTERY MFG.
Distribution A, 1X-18, 2X-29, 3X-39
Subject LEAD HYGIENE PROGRAM

I. *POLICY*

A. It is Globe-Union policy:

1. To pro[illegible] the health of its employees whenever [illegible] nature of their duties may expose them to a health hazard.
2. To prevent members of employees' families from becoming exposed to a health hazard arising out of Globe-Union employment.
3. To maintain its employees' blood lead concentrations below 60 micrograms/100 ml of blood (60 ug%).

B. Because a potential health hazard in Globe battery manufacturing plants arises from exposure to lead in the form of dust or fume, accepted industrial hygiene methods shall be utilized to protect employees from excessive exposure to and absorption of lead.

C. It is Globe-Union policy to control employee exposure to lead whenever feasible by means of

engineering controls, good housekeeping practices and good work practices, and to control lead ingestion by requiring good employee habits of personal hygiene. Respirators shall be worn only where provision of engineering and administrative controls is neither feasible nor adequate, or as a temporary or emergency measure until control of airborne lead exposure can be established by one of the preferred methods, or upon employee request.

II. *SCOPE*

This bulletin applies to each battery manufacturing plant or other facility where an employee may be exposed to airborne lead at or above 30 micrograms per cubic meter of air (ug/M^3) except for paragraph V.B.1, which applies wherever an exposure to airborne lead at any concentration may occur.

III. *REFERENCES*

SPB 1-953-04	Biological Monitoring Program for Lead Workers
SPB 1-953-07	Air Sampling Program
SPB 1-953-11	Respirator Wear Policy
SPB 1-953-12	Procedure for Care, Use and Maintenance of Respirators
SPB 1-941-09	Wash-Up and Clothes Changing Procedure
SPB 1-953-05	Work Clothing for Lead Workers in Battery Plants

IV. *RESPONSIBILITY*

A. The Plant Manager, with the assistance and counsel of appropriate Division and Corporate staff, is responsible for taking all measures

necessary to protect the health of employees and maintain a state of compliance with applicable Federal and/or State occupational health regulations.

The Plant Manager shall assign responsibility for each of the following functions:

1. Implementation of air sampling and respirator programs.
2. Establishment and implementation of programs for routine inspection, cleaning and preventive maintenance of all equipment exhaust and ventilation systems in the plant.
3. Establishment and implementation of plant housekeeping programs.
4. Establishment and implementation of work practice controls.
5. Establishment and implementation of programs to educate workers to the health hazard posed by lead and to train them in its control.
6. Establishment and implementation of personal hygiene surveillance programs.
7. Documentation of administrative solutions, where these are employed to control employee exposure and comply with regulations.
8. Implementation of programs of biological monitoring in the plant under the medical supervision of the consulting plant physician.

When the plant is under a major airborne lead citation, a single individual, the Plant Manager or his designee, shall coordinate the entire compliance effort in each plant; this includes monitoring of health hazards, the plant engineering

maintenance effort and motivation of employees toward good housekeeping and good work practices, as well as maintaining adequate communications between the plant and appropriate staff managers in Milwaukee headquarters.

B. The Corporate Medical Director is responsible for establishing biological monitoring and medical surveillance programs as needed to monitor and safeguard the health of employees.

C. The Corporate Manager of Health, Safety and Environmental Control is responsible for establishment and review of this policy and procedure, for establishment of industrial hygiene programs and for auditing compliance with this policy and procedure.

D. The Manager of Manufacturing Facilities is responsible for developing programs to provide engineering control of the lead hazard in the plants where this is necessary and for auditing the installation, operation and maintenance of the engineering control systems.

V. *PROCEDURE*

A lead hygiene program consisting of the following elements shall be implemented.

A. Housekeeping

1. Good housekeeping shall be maintained throughout each plant.
   a. Compressed air may not be used on any surface where lead accumulates.
   b. Vacuuming or washing are the accepted methods for cleaning. Only when they have been found ineffective may alternative methods be used.
2. A program of regular housekeeping inspections shall be instituted and maintained.

B. Employee Training

1. Any employee who may incur an exposure to airborne lead in any concentration shall be informed at once of the content of Appendices A and B in OSHA's Lead Standard.

   a. In battery plants, all employees shall be informed at the time of hire. Current employees shall be informed within 90 days of the receipt of Appendices A and B in the plant.

2. Any employee who may incur an exposure to airborne lead at or above 30 ug/M^3 shall participate in a training program which shall be repeated at least annually for each employee. For current employees, the initial training shall be completed by August 28, 1979. For new employees, the initial training shall be given prior to initial placement.

3. The training program shall encompass the following points:

   a. The content of OSHA's Lead Standard and its appendices A and B.

   b. Departments or work stations at which exposures above 30ug/M^3 could be experienced.

   c. The engineering controls and work practices which pertain to each employees job.

   d. Good personal hygiene practices required to minimize lead absorption.

   e. Good housekeeping practices.

   f. The purpose, proper selection, fitting, use and limitations of respirators.

   g. The purpose and description of the medical surveillance program and medical removal protection program including information on health hazards associated with excessive exposures to lead.

   h. A caution to employees not to routinely use chelating agents to remove lead from their bodies and not to use these agents at all unless under the direction of a licensed physician.

   i. The contents of any OSHA compliance plan in effect.

   j. The distribution to the employees of any information made available to the Company by OSHA concerning the Occupational Safety & Health Act, its regulations, or the Lead Standard.

C. Engineering Controls

1. Provision and maintenance of adequate ventilation on equipment and at work stations to capture lead dust or fume at the point of its generation.

2. A program of regular monitoring of ventilation system performance designed to permit early detection and correction of any deterioration in ventilation system performance.

3. A program of regular visual inspection of oxide storage and transfer systems to permit the detection and correction of oxide leaks.

D. Biological Monitoring

A biological/medical surveillance program to monitor employees' lead absorption and protect their health.

E. Air Sampling

A program of regular air sampling to monitor employee airborn lead exposure, designed to permit early detection and correction of significant increases in exposure, whether these arise from increased air-lead concentration or increased duration of exposure.

F. Respirator Wear

A program of respirator wear to provide employees with temporary emergency protection against excessive exposure to airborne lead.

G. Periodic Review of Industrial Hygiene Records

A program of regular review of each employee's industrial hygiene exposure data, supplemented by records of duration of exposure (overtime work), employee work practices and general workplace conditions.

This will permit early detection and correction of poor housekeeping practices, inadequate and/or malfunctioning engineering controls, poor work practices and weekly exposures, the duration of which may be inappropriately long, in view of the existing airborne lead concentration levels.

H. Personal Hygiene Program

1. Smoking, eating and drinking (except from fountains) are permitted only in the cafeteria and main office area of battery manufacturing plants where hands and face washing facilities are available and the use of which is enforced.

2. Tobacco products, non-food chewing products (e.g. chewing gum), purses, and unapplied cosmetics are permitted only in the locker room, cafeteria, and main office area of battery manufacturing plants.

3. Wash-up prior to eating or smoking and daily showers at end of shift are *required* for all employees who are exposed to airborne lead at or above the permissible exposure limit or who work in lead oxide areas. It is recommended that all other employees also do this.

4. All employees exposed above the permissible exposure limit shall be provided with separate work and street clothes lockers.

5. At least every other working day, work clothing changes are required for all employees who are exposed to airborne lead at or above the permissible exposure limit or who work in lead exposure areas. Safety work shoes are also required for these employees. Work clothing and work shoes are also required for these employees. *Work clothing and work shoes of these employees may not be taken out of the plant*, in order to prevent exposure of family members to lead. It is recommended that all other employees also do this.

6. A program of surveillance of personal hygiene practices including, but not limited to, the above measures shall be implemented, the results of which shall be used to correct improper or inadequate prac-

tices in order to reduce resulting lead absorption.

I. A program of regular review of the results of the personal hygiene surveillance program and of employee industrial hygiene and biological monitoring data shall be conducted by the plant nurse to determine what, if any, additional measures are necessary to prevent or reduce lead absorption.

J. In instances where employees are threatened with excessive exposure to or absorption of lead, plant management shall undertake to identify the source of the heightened exposure and reduce or eliminate it. To accomplish this:

1. Ventilation and exhaust system performance and records should be checked.
2. Production equipment should be checked for leaks, excessive operating temperature and other evidence of improper condition or function.
3. Housekeeping performance and records should be reviewed.
4. Employee work practices should be reviewed.
5. Employees hygiene practices should be reviewed.

Appropriate steps shall be promptly taken to correct any inadequacies discovered.

K. Full compliance with required housekeeping, work practices, respirator wear and personal hygiene measures shall be achieved through plant disciplinary procedures where necessary.

L. Recordkeeping

1. All employee industrial hygiene and biological monitoring/medical records shall be kept for at least 40 years or for the duration of employment plus 20 years, whichever is longer. Medical removal records shall be kept for at least the duration of employment.
2. All personal exposure air sampling results and blood lead sampling results will be reported in writing to the employee sampled within five days of receipt of results.

[BIOLOGICAL MONITORING PROGRAM]

(Beaudoin Aff., Ex. D)

JOHNSON CONTROLS

STANDARD PROCEDURE

Division GLOBE

Section HSECD

Date Effective 09-01-81

Date Revised 03-25-83

Bulletin No. 3-953-04

Endorsed by

VP BATT. MFG., DIR. PERS. & IND. RELATIONS

Distribution 3X-39 & Special

Subject

BIOLOGICAL MONITORING PROGRAM FOR BATTERY DIVISION EMPLOYEES

I. *SCOPE*

This standard procedure establishes the program for biological monitoring and follow-up for those employees whose duties may expose them to lead.

II. *STANDARD PRACTICES*

A. Applicability

This procedure applies to all Battery Division employees experiencing occupational exposures to lead.

B. References

1. SPB 3-950-20, Medical Surveillance Program
2. SPB 3-950-21, Preemployment Examinations
3. SPB 3-954-01, Fetal Protection Program

4. IHP 1-404, Assessment of Lead Exposure and Absorption (Industrial Hygiene Procedure)
5. HSP H-451, Biological Monitoring—Lead (Health Service Procedures)

C. Objectives

To protect the health of its employees whenever the nature of their duties may expose them to occupational health hazards and to prevent any employee from having an occupational exposure which may aggravate any other preexisting disease or condition.

D. Responsibilities

1. The plant manager shall be responsible for the implementation of this standard procedure through the plant physician, nurse and personnel manager.
2. The Manager of Health, Safety & Environmental Control is responsible for the establishment and review of this standard procedure and for auditing compliance thereto.

E. Placement

1. Preemployment

To evaluate suitability of placement in lead exposure, applicants for employment in a battery manufacturing plant will have a blood sample drawn as part of their preemployment physical examination, the results of which must be reviewed by the plant nurse and/or physician prior to hiring. This will be used to establish the employee's base-line blood lead, hemoglobin and ZPP levels.

2. Transfer Placements to Lead Areas

   a. No employee of childbearing capability will be placed in jobs where the airborne lead exposure is at or above 30 ug/m³ and the blood lead level of any of the incumbents over the past year (transfers excluded) was at or above 30 ug%.

   b. To ascertain suitability of transfer into lead exposure, container molding plant transfers into the lead casting area will have a pretransfer evaluation including blood lead, hemoglobin and ZPP. The results must be reviewed by plant nurse and/or physician prior to transfer.

   c. Battery plant transfers into lead exposure areas, i.e., at or above 30 ug/m³, will have:

      1) A pretransfer evaluation including blood lead, hemoglobin and ZPP taken no more than three weeks in advance, the results of which must be evaluated by the plant nurse and/or physician prior to transfer.

      2) Post-transfer monthly assessment for first three months in exposure, including a blood lead, hemoglobin and ZPP analysis.

   3. All placements (initial or transfer) are subject to prior medical review and approval by the plant physician.

F. Sampling Frequency

   1. In battery plants a ZPP analysis (with interpretation to the employee) will be executed at the time each blood lead sample is drawn.

   2. In poly plants an FEP analysis shall accompany blood lead analysis (with interpretation to the employee on receipt of the results).

   3. Blood samples will be drawn, according to the following schedule, for blood lead, hemoglobin and protoporphyrin analysis on all battery manufacturing plant employees, and on those molding plant employees who cast lead.

      a. Monthly (without exceptions)

         1) All newly hired battery manufacturing and molding plant lead casting employees, except office staff, for the first three months of their employment.

         2) All employees newly transferred into lead exposure at or above 30 ug/m³ for the first three months of such placement.

         3) All employees whose most recently measured blood lead level is at or above 40 ug% and/or whose most recently measured ZPP level is at or above 60 ug%.

         4) All employees of childbearing capability whose most recently measured blood lead level is at or above 30 ug%.

         5) All employees who currently are removed from lead exposure due to lead absorption or lead effect, during the period of their transfer or medical leave.

         6) All employees returning from lay off/leave of two months or longer, who will be exposed to airborne lead of 30 ug/m³ or greater, for the first three months of such placement.

b. Every two months (bi-monthly)

All employees of childbearing capability whose most recently measured blood lead levels are 20-29 ug%.

c. Every three months

All employees of childbearing capability whose most recently measured blood levels are less than 20 ug%.

d. Every six months

All battery manufacturing plant and molding plant lead casting employees whose blood lead is under 40 ug% and whose protoporphyrins are under 60 ug% after the first three months of employment.

4. A ZPP analysis only will be done every two months (bi monthly) for:

   a. All employees who work in lead exposure greater than 30 ug/m^3 and whose most recent blood lead level is less than 40 ug% and/or most recent ZPP reading is less than 60 ug%.

   b. All employees of childbearing capability whose most recently measured blood lead levels are 20-29 ug%, in the monthly intervals between blood lead samples.

5. Under all circumstances any change from the above specified sampling frequency shall be established only upon order of the plant physician when, in his professional judgement, other biological indices of lead effect indicate a change in order to protect the health of an employee.

G. Processing and Identification of Samples

1. Blood samples shall be drawn in the tube provided by ESA Laboratory and transmitted by the *fastest* means which can be determined by contacting the local post office, UPS or Federal Express office.

2. Refer to HSP - H 451-03 for specifics of procuring supplies, specimen identification and shipping.

3. All blood samples collected under this program shall be analyzed at the ESA Laboratory in Bedford, Massachusetts.

H. Results

1. Copies will be mailed by the laboratory to the plant nurse, the plant physician, the Medical Director, and two copies will be sent to the Health, Safety and Environmental Control Department, X12, Milwaukee.

2. All employee blood lead sample results will be reported to the affected employee, in writing, on Form 5-29, within five days of receipt in the plant.

I. Recordkeeping

1. Recording of biological data will be done on the "Biological Monitoring Record," Form 10-128 maintained for each employee. The identifying information should include the employee's name, SS number and Globe plant.

2. The Biological Monitoring Record constitutes a *legal medical record.* For this reason, individual airborne lead personal exposure data will *not* be recorded on Form 10-128.

3. The Biological Monitoring Record itself is a historical occupational medical record. It should include:

   a. Job title, work station site number and other pertinent data for each employee, updated at each job transfer.

   b. A record of unusual complaints, hospitalizations, etc.

4. A copy of the Biological Monitoring Record may be released to the employee's personal physician on receipt of the employee's signed authorization. It must be reviewed with the employee upon request.

5. Monthly, the removal or restriction (including overtime restrictions) for any employee from lead exposure, and the subsequent return to unrestricted work, is to be reported to the Health, Safety & Environmental Control Department, X12, Milwaukee, on Form 5-27.

6. Removal from lead exposure is OSHA reportable only if the transfer is based on the physician's medical judgement because of clinical or subclinical manifestations in the employee. Usual recordkeeping of occupational illness is to be instituted with lost and restricted days recorded in Column 7.d. of the OSHA 200 form.

   Removal based solely on numerical criteria is *not* OSHA reportable and need not be recorded on the OSHA 200 form.

J. Records Retention

Medical and biological records must be kept for at least 40 years or for the duration of employ-

ment plus 20 years, whichever is longer. Transfer and medical leave of absence records must be kept for at least the duration of employment.

K. Actions Required in Plant

1. General

   a. Each employee's blood lead record will be reviewed by the plant nurse with each new entry to determine need for further follow-up.

   b. As blood lead levels exceed the 40 ug% and higher decade markers, an Assessment of Lead Absorption should be conducted to reduce lead absorption. In general, the following factors should be addressed when lead absorption is reviewed:

      1) Respirator wear—proper wear time, enforcement, facial hair, proper respirator worn, and fit testing. Consideration should be given to imposing respirator wear at 40 ug/m^3.

      2) Hygiene practices—including wash-up, showers, use of tobacco products, and clothing contamination.

      3) Lead exposure levels—proper functioning of engineering controls, proper work practices being followed.

      4) Other factors—including overtime, outside job activities, and worker training.

   These factors are discussed further in Industrial Hygiene Procedure Bulletin No. 1-404, "Assessment of Lead Exposure and Absorption."

c. Physician Review

1) The plant physician shall review the employee's biological monitoring record and airborne lead exposure records each time lead absorption has reached 50 ug%.

2) The physician will review and interpret all other biological indices, particularly those that assess interference with heme synthesis or renal function, upon receipt of these results.

3) Any individual who has medical complaints will see the plant nurse and, if necessary in the nurse's judgement, will be referred by the nurse to the physician for documentation of the nature of the employee's illness.

2. Blood lead levels 40 ug% or greater or ZPP levels 100 ug% or greater.

a. Take prompt action to reduce the employee's absorption of lead.

1) Work Practice Review shall be initiated by the immediate supervisor. Review will include adherence to respirator, work and personal hygiene practices.

2) Impose full shift respirator wear.

3) Industrial Hygiene and Safety Coordinator should initiate assessment of respirator fit, to include: review of facial features, proper respirator being worn, adherence to wear time requirements and possible refit testing.

3. Blood lead level transfer criteria and action plan. Action required by "a" through "d" of

this section will be implemented through the following schedule: 03/01/83—05/31/83—Blood lead results of 60 ug% or greater, confirmed.

06/01/83—08/31/83—Blood lead results of 60 ug% confirmed *or* blood lead average of 55 ug% and above, whichever comes first. (Calculate average of last three blood sample results, or all of those conducted over the last six months, whichever is longer.)

09/01/83—Fifty (50) ug% blood lead average and above.

a. Except where the employee's most recent blood lead result is 40 ug% or less, transfer employee to a work location where the lead exposure is consistently below 30 ug/m^3, and where the lead absorption level of employees indigenous to that area is consistently below 40 ug%.

b. Monthly, the plant physician will follow-up the employee beginning with receipt of the blood lead result which triggers the transfer and until the lead exposure restriction is removed.

c. Employee may be returned to lead exposure above 30 ug/m^3 when blood lead level is confirmed below 40 ug%. Exception: employees transferred because of blood lead average of 55 ug% and above during period 06/01/83—08/31/83 may be returned to lead exposure above 30 ug/m^3 when the blood lead average drops below 49 ug%.

d. Consult with Health, Safety and Environmental Control Department.

4. Employee of childbearing capability (Refer to II.B.3).

   a. Individual with blood lead at or above 40 ug% (confirmed).

      1) Implement full shift respirator wear.

      2) Transfer as soon as possible to an "acceptable" work station as defined in SPB referenced in II.B.3. Implement Medical Removal Protection benefits.

   b. Individual with blood leads 35-39 ug%.

      1) Implement full shift respirator wear.

      2) After two readings in this range encourage voluntary transfer. Restrict exposure to 40 hours/week in air lead levels greater than 30 ug/m^3.

      3) After four readings in this range, transfer as in II.K.4.a.2. above.

   c. Individual with blood leads 30-34 ug%.

      1) Implement full shift respirator wear.

      2) After three readings in this range, encourage voluntary transfer. Institute overtime restriction as in II.K.4.b.2. above.

      3) Give priority to transfer to an acceptable opening in the same job class.

      4) After six readings in this range, transfer as in II.K.4.a.2. above.

   d. If an employee's blood lead rises to greater than 30 ug%, institute steps as outlined in II.K.4.a., b., c., above depending on blood lead level.

NOTE: Actions at steps b and c are triggered by the *total* number of consecutive readings at or above 30-39 ug%.

5. The plant physician may recommend removal or restriction of an employee on the basis of medical judgement other than the above.

6. All information, related to the problems uncovered and the corrective action taken as a result, will be communicated in writing to the plant physician and documented. A copy of this information will be sent to the Health, Safety and Environmental Control Department, X12, Milwaukee.

L. Medical Removal Protection (MRP)

When an employee is removed from lead exposure pursuant to this practice, medical removal protection benefits required by OSHA regulation will be provided as follows:

1. In the case of lead related transfers, the employee shall be paid average straight time hourly earnings (as computed for holiday pay) for actual hours worked or actual earnings, whichever is higher, until he/she is returned to his/her original job or for 18 months whichever is shorter. This applies to all transfers under Section II.K.4. and to those transfers in Section II.K.3. where the employee had an airborne lead exposure of at least 30 ug/m^3. This also applies to all transfers under Section II.K.5. except that the 18 months limitation does not apply.

2. In cases of occupational disease pertaining to lead absorption, as determined by the com-

pany physician and for periods during which the employee is eligible for workers compensation, the employee shall be compensated at average straight time hourly earnings (as computed for holiday pay) less any such workers compensation benefit received for a period not to exceed 18 months. In such cases, the employee shall retroactively receive compensation for any waiting period prescribed by the Workers' Compensation law.

SPECIAL DISTRIBUTION

Battery Division Plant and Occupational Health Nurses

[MEDICAL SURVEILLANCE PROGRAM]

(Beaudoin Aff., Ex. F)

JOHNSON CONTROLS

STANDARD PROCEDURE

Division GLOBE

Section HSECD

Date Effective 09-01-74

Date Revised 02-10-83

Bulletin No. 3-950-20

Endorsed by VP BATT MFG., DIR PERS & IND REL DIV MED DIR

Distribution 3X-39 & SPECIAL

Subject MEDICAL SURVEILLANCE PROGRAM

I. *SCOPE*

This standard procedure is applicable to employees and applicants for employment at all domestic Globe Battery Division facilities.

II. *STANDARD PRACTICES*

A. Responsibility

The Globe Battery Division is to provide medical evaluations to each employee or applicant prior to employment and to assure that neither will be placed on a job where he/she is not physically and mentally capable of performing that job safely, protecting his/her health and that of fellow workers.

B. Pre-employment Examinations

1. Prior to hiring, each applicant considered for employment in the following positions shall have a complete medical history and a thorough physical evaluation by the plant physician:
   a. All manufacturing plant salaried positions.
   b. All staff and sales salaried positions in position grade 52 and above.
   c. All staff and sales salaried positions in position grade 51 and below, aged 35 and older.
   d. All hourly positions.
2. Applicants for these positions must understand that hiring eligibility is subject to the concurrence of the company designated physician.
3. Prior to hiring, each applicant for salaried employment not required to undergo the pre-employment in II.B.1. above, shall complete a pre-employment medical history which shall be reviewed by the facility nurse and/or physician.
4. All female applicants for battery manufacturing hourly jobs will be required to provide medical documentation of inability to bear children. All female applicants for placement in salaried jobs in battery plants where blood lead in the last year has been $\geq$ 30 ug% must present the same medical documentation. This also applies to placement in jobs in poly plants where blood leads $\geq$ 30 ug% were recorded in the past year.
5. Medical findings which require a physician's attention will be explained to the applicant or

new employee, who shall be referred to his or her personal physician.

6. Under certain circumstances medical action may be requested of an applicant as a condition of employment. Any medical condition not controlled or requiring treatment shall be treated to the point of correction or acceptable medical control prior to initial placement.
7. Whenever the examining physician restricts an applicant for physical or mental health reasons, the decision of the physician shall be final. An applicant restricted for medical reasons should be placed on a job consistent with his/her capabilities.
8. The personnel manager is responsible for determining if a job consistent with the restrictions of a prospective employee is available.
9. The medical history and results of the physical examination are to be treated as confidential information and kept in locked medical files at the plant under the control of the plant nurse and the plant physician. Information contained in such files is to be released to any third party only over the employee's signature. The company agrees to provide each employee a complete copy of his/her company medical file upon his/her written request provided the file is first reviewed with the employee by the company doctor and/or nurse. The frequency is not to exceed once per year.

C. Periodic Occupational Examinations

1. General

   A medical examination(s) shall be made under any circumstance wherein an employee is exposed beyond a defined action level to a

known toxic agent or health hazard or complains of symptoms which may be related to exposure to such materials, such as lead, arsenic, cadmium, silica, acrylonitrile, and noise. Frequency and content of these examinations will be specified in sections dealing with the specific material, or, where absent, by the Division Medical Director.

2. Respirator Wear

A medical examination will be made whenever an employee complains of a physical problem or breathing difficulty when using a respirator provided there is not an approved respirator which will alleviate the problem.

3. Lead Exposure

A periodic occupational examination includes a medical history, required laboratory tests and a physical examination by the company designated physician. The medical history must be updated and blood lead sampling must be performed for each examination. Other portions of the examination may be waived if they were performed within the previous year, and, in the physician's judgement, the history or biological monitoring results show evidence of not requiring further follow-up at this time.

a. Each employee who had a blood level of 40 ug% or greater during the preceding 12 months shall be examined at least annually. This includes examinations covered under Section II, subparagraphs B.; C.3.b.; D.2., 3., and 4.

b. Prior to initial assignment to a work station or job for which airborne lead concentrations are at or above 30ug/M^3.

c. Any employee who has medical complaints or symptoms should see the plant nurse. If necessary in the nurse's judgement, the employee will be referred to the appropriate physician to document the nature of the employee's illness.

d. Each employee currently under work restriction, preventive transfer or medical leave of absence (due to a risk of sustaining material impairment to health) will be examined at a frequency to be determined by the plant physician.

e. An employee may submit a request to the plant nurse for a consultation with the plant physician for advice concerning lead exposure and its effects on the employee and the family's health.

4. Arsenic Exposure

An employee shall have complete medical history, a physical examination and appropriate laboratory tests prior to assignment where arsenic is used and yearly thereafter when the exposure is at or above 5 ug/M^3. Until a separate standard procedure bulletin on "Periodic Occupational Medical Examinations —Arsenic" is issued, the plant nurse shall contact the Division Medical Director for the specific content of this examination.

5. Silica Exposure

An employee exposed to silica will have a medical history, a physical examination and appropriate laboratory tests prior to a job assignment and yearly thereafter. Until a separate standard procedure bulletin on "Periodic Occupational Medical Examination—Silica" is

issued, the plant nurse shall contact the Division Medical Director for the specific content of this examination.

6. Acrylonitrile Exposure (Carcinogenic Exposure)

   An employee shall have a complete medical history, a physical examination and appropriate laboratory tests prior to assignment where acrylonitrile is used and yearly thereafter when the exposure is at or above 1 ppm. Until a separate standard procedure bulletin on "Periodic Occupational Medical Examinations —Acrylonitrile" is issued, the plant nurse shall contact the Division Medical Director for the specific content of this examination.

D. Medical Re-Examination

1. In signing the company "Application For Employment," Form 10-81B, each applicant agrees to a medical examination prior to employment, periodically thereafter when requested or required, and at the time of termination, if required.
2. Re-examination of an employee may be required anytime the plant nurse or physician deems it medically advisable.
3. Request for re-examination of an employee may be made by members of plant management with concurrence of the plant nurse or physician.
4. To assure proper job placement, re-examination by a company designated physician will be required upon the employee's return from a medical leave of absence (either personal or occupational) which is considered serious in

the judgement of the plant nurse and/or physician. A medical statement from a physician will be required for granting a non-occupational medical leave of absence, to be reviewed and approved by the plant nurse and/or physician.

5. A re-examination shall be required upon the employee's return from a layoff or strike of two months or longer under paragraphs II.C. 2. and 3. Where the employee has had other employment during the period of layoff or strike, the re-examination shall be required regardless of the length or strike .

E. Truck Driver's Physical Examination

1. Truck drivers are required by D.O.T. rules to have a current physician's certificate. These certificates are valid for 24 months.
2. Copies of drivers' health history and physical examination will be kept in medical files at the plant, under the control of the plant nurse and physician.
3. The Medical Examiner's certificate will be transmitted to the plant's Manager of Transportation or Personnel Manager for inclusion in the employee's personnel records according to D.O.T. regulations.
4. Plant medical staff will assure that examinations are given and certificates renewed within the 24 month requirement.

SPECIAL DISTRIBUTION

All Plant Occupational Health Nurses
All Plant Physicians

[PERIODIC OCCUPATIONAL MEDICAL EVALUATION]

(Beaudoin Aff., Ex. G)

GLOBE-UNION INC.

STANDARD PROCEDURE

Division CORPORATE

Section CORP. RELATIONS

Date Effective 08-01-79

Date Revised ORIGINAL

Bulletin No. 1-950-22

Endorsed by VP CORP. REL. VP & GM BATT DIV
CORP. MED. DIR.

Distribution A, 1X, 11, 3X-39 & SPECIAL

Subject PERIODIC OCCUPATIONAL
MEDICAL EVALUATION—LEAD

I. *PURPOSE*

This bulletin defines the specific procedure for conducting and documenting yearly and periodic examinations for lead exposure

II. *SCOPE*

A. To insure that no employee has any permanent disability or irreversible toxic effect from lead exposure.

B. The early detection of any non-occupational disease state which continued exposure to lead would aggrevate the condition.

C. Education of the employee and a check of his knowledge concerning the hazards associated with his job and exposure to lead.

D. To instruct the employee in proper use of protective equipment, its use where indicated.

E. To provide standardized health data which will assure quality control of the biological monitoring program.

F. To provide standardized data which lends itself to statistical and epidemiological analysis for improvement in engineering and hygiene programs or assurance that all programs are sound and cost effective.

III. *REFERENCES*

SPB 1-950-20 and 21, 1-953-04

IV. *IMPLEMENTATION*

A. Frequency of Evaluation

1. Yearly for employees exposed to airborne concentrations of lead at/above 30 mcg/M^3.

2. Within twelve months of a blood lead at or above 40 mcg/100 ml if not examined under subparagraph IV.A.1 of this procedure.

3. When, in the judgement of the plant physician, an employee has complaints or symptoms which must be differentiated from those of lead effect.

B. Periodic Evaluation

1. Employee complaint or symptoms from questionable effect of lead.

a. Interim history (form 10-86).

b. Extent of physical examination shall be at the discretion and professional judgement of the company designated plant

physician to adequately evaluate the employee.

c. Additional laboratory tests shall be adequate to properly evaluate the employee's symptoms and to make a sound differential diagnosis of the causes of the symptoms.

2. Yearly evaluations required for employees exposed at or above the action level of lead or absorption of lead above 40 mcg/100 ml blood.

a. Re-examination history shall be complete on Form No. 10-86. The history shall be reviewed by the plant nurse. Corrections shall be noted by the nurse and discussed with the employee prior to referral to the company designated plant physician for examination and evaluation.

b. Physical re-examination shall be completed on Form No. 10-86.

1. The extent of the examination shall be thorough to include skin, fundiscopic, ostoscopic, chest, abdomen, musculoskeletal, and neurological assessment for detection of any manifestations of effects due to lead exposure.

c. Laboratory tests

1. CBC and differential.

2. A blood chemistry of at least SMA12 to include glucose, creatinine and BUN.

3. Zinc protoporphyrin, Urinary d-ALA Spot., blood lead.

4. Urinalysis with microscopic examination.

d. Special laboratory tests

1. Pulmonary spirometry when indicated by history of respiratory difficulty or previous difficulty with respirator wear.

2. Audiogram when in exposure at or above 90 dbA.

e. A summary of findings shall be made in writing and approval for placement shall be made in the appropriate space on Examination Form 10-86.

f. Medical classification (A—qualified for any type of work; B—has medical condition requiring permanent restrictions, such as, no lead exposure, no respirator wear, no heavy lifting, etc.) shall be reviewed on any required changes from the previous classification explained. Temporary restrictions shall be communicated in writing on Form 10-86 as to nature, extent and duration, but shall not affect the permanent medical classification unless so indicated.

g. New abnormal findings (i.e., diabetes, hypertension, etc.) shall be reported to the employee and the employee shall be referred to his personal physician. Upon request, a copy of the laboratory report and physical findings shall be sent to his personal physician.

SPECIAL DISTRIBUTION:

Battery Division Branch &
Milwaukee nurses (14)

[POLICY GUIDELINES FOR WOMEN IN LEAD EXPOSURE]

(Beaudoin Aff., Ex. J)

GLOBE-UNION INC.

COMPANY CORRESPONDENCE

[Signature Omitted]

TO: Battery Plant and Personnel Managers

ATTENTION:

SUBJECT: Women In Lead Exposure

FROM: Robert W. Schindler
Corp. Health & Safety

DATE: June 9, 1977

Attached are policy guidelines for the employment in lead exposure of women capable of bearing children.

This change has come about slowly as more and more medical opinion and evidence is persuasive of the risk to the unborn, developing child.

We have stopped short of excluding women capable of bearing children from lead exposure, but do feel strongly that those women who are working in lead exposure (defined herein) and those women who wish to be considered for employment to be advised that there is risk, that we recommend *not* working in lead if they are considering a family, and further that we ask them to sign a statement that they have been advised of this risk.

The enclosed gives some background behind this decision, outlines the implementation of the policy, covers a suggested content in such a "recital of risks" and a copy of the form to be signed.

We suggest that you review this carefully, raise any questions you may have with me and make plans to review it with the union committee before implementing.

A standard procedure bulletin covering this adopted policy will be issued at a later date.

Globe-Union shares a dilemma along with others who employ women in lead exposures. We are faced with EEO and Title VII on one hand with risk of charges of sex discrimination if we exclude women as a class from lead, on the other hand, with the liability risk of being charged by an affected employee with injury to fetus or lead induced abortion if we allow them to work in lead exposure.

We have seen fit *not* to exclude women as a group from Battery manufacturing operations as a written corporate policy, however, it is becoming increasingly clear that medical concern for the unborn child of a female working with lead or lead oxide is growing in a number of quarters. For the foreseeable future, we see this as a problem despite our continuing best engineering efforts.

Recent evidence is the adoption by the Battery Council International's Environmental Health Committee that "member companies do not employ fertile, gravid, or lactating females in the lead industryies until such time as adequate information has been developed regarding the effect of lead under present exposure conditions".

It is also evident in OSHA's proposed standard on lead when it raises the question, "To what extent are there groups with increased susceptibility to lead in the working population, such as women of childbearing age and should such increased susceptibility, if it exists, be considered in establishing a standard for lead?"

Recent studies of the toxicological effects of exposure to lead, OSHA further states, "raises the serious possi-

bility that the blood lead in the mother might harm the fetus without producing any clinical symptoms of lead exposure in the mother."

We at Globe-Union have taken the position that the mandate of OSHA is to protect the health of *employees.* Although we all share concern, protection of the health of the unborn child is the immediate and direct responsibility of the prospective parents. While the medical profession and the company can support them in the exercise of this responsibility, it cannot assume it for them without simultaneously infringing their rights as persons.

We believe that pregnancy is almost always a voluntary act and that the subsequent bearing of a child is voluntary. Since not all women who can become mothers wish to become mothers (or will become mothers), it would appear to be illegal discrimination to treat all who are capable of pregnancy as though they will become pregnant.

For these reasons and based upon the current situation, we believe that the decision in each case should properly be made by the individuals immediately involved. The parents, those who bear the direct responsibility of the well-being of the fetus, need to be well informed so that their decisions are made on the basis of full knowledge of the facts and understanding of the implications and risks of occupational exposure of the fertile woman to lead.

OSHA has tried to meet this problem in their proposed "Inorganic Lead Standard" by including a pregnancy test as part of required pre-employment and annual periodic medical examinations. We at Globe-Union take exception to that approach because according to some authorities, a state of pregnancy cannot be determined early enough to prevent possible significant risk to the health of the fetus.

We propose, therefore, that all women between ages of 18 and 49 who can conceive be seen by our plant nurse or our company physician and receive health counseling as to the hazards of lead absorption to any fetus she might conceive and then the female employee be guided by her personal physician to determine whether her personal situation and medical history call for a limitation on her current occupational placement.

We see our role, in view of the present day understanding of the possibility of harm to an unborn child, and pending definitive legal guidelines, as providing facts of the implication and risks of occupational exposure to lead to the women capable of conception working under our roof so they may make an informed decision.

I. *Implementation of Policy*

A. Active Employees

1. Determination by medical department of women currently in lead exposure who are able to bear children. Lead exposure defined as airborne lead concentration in excess of 50 micrograms/M^3 or blood lead levels exceeding 30 micrograms/100 Ml.
2. Recital of risks to individual women by nurse or company physician.
3. Summary statement of Risks to be signed by employee.
4. Arrange transfer to non-lead areas of women who wish to be moved as bona fide openings or bidding procedures make such transfers possible.

B. Prospective Employees

1. All women capable of bearing children considered for employment in battery manufacturing

areas where airborne lead concentrations are greater than 50 micrograms/M ^{3} (TWA) will be advised of the existence of risks to any fetus she may conceive.

2. She will be advised that we do *not* recommend placement in lead exposure if she wishes to have children.
3. If she still wishes to be considered for placement she will as part of the medical examination procedure be asked to sign a "Summary Statement of Risks". Signature to be witnessed by employment interviewer or nurse.

RECITAL OF RISKS

"In the practice of industrial medicine we sometimes don't know all we'd like to know. Falling into this category is the effect of a toxic substance like lead on the human being particularly the unborn, developing child. Lead effect on the adult person is well understood and we keep people safe and healthy even though they may be working with a toxic substance.

But when it comes to the effect of lead on an unborn child, we know a lot less, as you can well imagine; but we do know enough to be able to tell you that there are some risks. Risks you should be aware of because you work in lead.

While each individual reacts differently there is evidence, though not scientifically conclusive, that women exposed to lead have a higher rate of abortion than those in the general population. The evidence is not as clear, for example, as the relationship between cigarette smoking and cancer, but it is enough for us to make plain that if you conceive you should recognize that staying on the job and working with lead oxide may well have an effect on your ability to carry your child to term.

As far as the effect on the unborn child is concerned, even less conclusive medical information is known but even as much of the information regarding the health effects of chemicals, food additives, pollutants, etc. is learned through animal experimentation, there is evidence from that source that animals fed or exposed to airborne lead run the risk of having congenitally affected offspring.

We are controlling the air exposure, providing protective equipment when necessary and monitoring your absorption by blood tests and are confident that if you do your part with good work practices and hygiene habits, you can work without concern for your health; but in the event you become pregnant it adds another dimension to the problem. Lead levels which are harmless to women at work in our plant are possibly sufficient to cause damage to the embryo and developing infant. Not only is it current exposure but since lead in the body sometimes takes many months to be excreted, there can be a risk even after you leave exposure. There is some evidence that fetus may be affected rather quickly following conception. This is a possibility that you will have to weigh in your own mind, if in fact you want children, or if you are planning on children at a later date, or are concerned that you may conceive unexpectedly. Only you can make the decision to run that risk. We would have to say that it is, medically speaking, just good sense not to run that risk if you want children and do not wish to expose the unborn child to risk, however small, and so recommend that you counsel with your family doctor and advise us of your wishes to transfer.

I'm here to answer any medical questions you may have. Any questions you may have about job change or transfer now or at a later date should be taken up with the Personnel Manager."

III. Summary Statement of Risks for Women Working in Lead Exposure

I have this day had the opportunity to listen to an explanation of the risks that any unborn child of mine might run by virtue of my exposure to lead in the course of my work at Globe-Union and to ask any questions I have about such risks.

I understand that the decision is mine to make, but the Company feels an obligation to inform me that there is a risk and to recommend from a medical point of view, that if I wish to have children that the risk is high enough to the unborn child to recommend that I *not* work at a job in lead exposure.

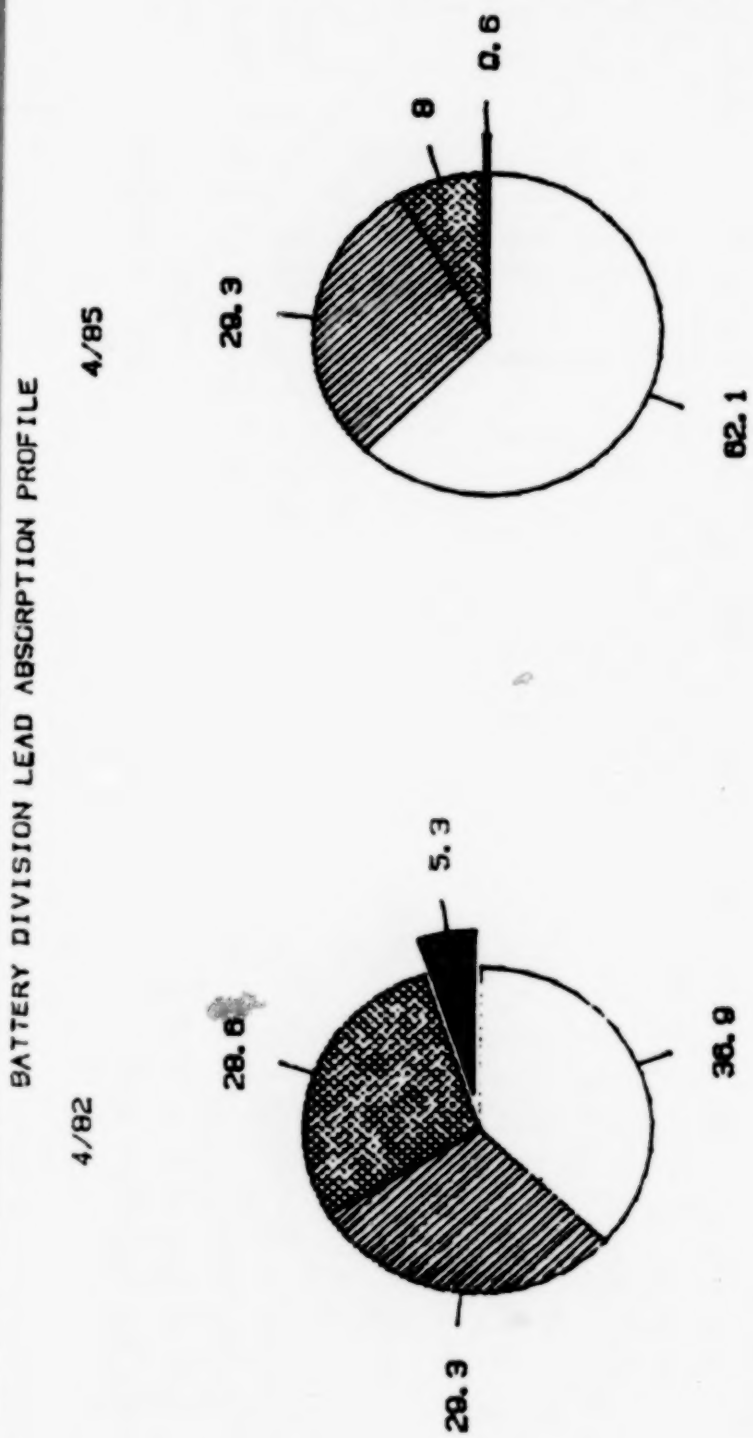
I have read and understand the above statement.

_____

Witness (interviewer) _____

Date _____

(Beaudoin Aff., Ex. L)



(Beaudoin Aff., Ex. M)

JOHNSON CONTROLS, INC.—BATTERY DIVISION

BLOOD LEAD PROFILE

Blood Lead Range, ug/100 ml	Percentage of the Manufacturing Workforce			OSHA Projection
	4/30/82	4/30/83	4/30/84	4/30/85
> 60 ug/100 ml	0.4	.07	.09	.02	.05
50-59 ug/100 ml	4.9	1.6	1.3	.62	5.5
40-49 ug/100 ml	28.6	12.1	9.3	8.0	23.3
30-39 ug/100 ml	29.3	31.8	28.7	29.3	
20-29 ug/100 ml	24.2	30.9	32.9	32.7	
< 20 ug/100 ml	12.7	23.4	27.7	29.4	
Total < 40 ug/100 ml	66.2	86.1	89.3	91.4	70.1
Total ≧ 40 ug/100 ml	33.9	13.8	10.7	8.6	29.3

* OSHA projection assumes compliance with 50 ug/m³ air standard (40 CFR 52963).

[EXCERPTS OF FISHBURN TESTIMONY]

(First Aff. of Jaspan, Ex. A)

[11] Q How does lead enter the body?

A Lead—inorganic lead enters the body by primarily inhaling air contaminated with metal oxides, or metal compounds of lead, as well as by ingesting it, which you can do on food or contaminated fingers, by contaminating food. It is then absorbed through the gut, a small amount.

Q How is the lead exposure of an individual measured?

A If you're speaking of lead exposure of a worker, the exposure is—is measured by monitoring the air, taking breathing zone samples from the individual worker on the job. If you're speaking of monitoring the worker in exposure you're doing this with blood-leads. And in addition to this we monitor the effect of the lead on the metabolism of hemoglobin, which is in the red blood cell.

Q What is, you say—what is a blood-lead?

A A blood-lead is a measure of the amount of lead that is present in the circulation of which we draw venous blood. [12] It's a measurement of recent past exposure.

Q What were the other measurements you've indicated?

A The other measurements that we monitor routinely for lead effect is hemoglobin, and the protoporphyrin, for it's the earliest easy thing that we have to measure to tell us the unwanted or adverse effect or interference of lead with making hemoglobin. If it proceeds far enough the reason we do hemoglobin is, one, make sure we do not have people who are severely anemic in lead, and that we do not have people who become anemic because of the effect of lead, and interfering with the production of hemoglobin.

* * * *

[13] Q What is the difference between measurement of the protoporphyrin or the hemoglobin as opposed to—compared to the blood-lead, are they the same thing or different things?

A We are measuring only the amount of lead that's in circulation when the blood-lead is measured, and what we're measuring for with the other test is what effect is it having on the individual, so that we're more concerned about protecting the individual against the unwanted effects regardless of the blood-lead.

Q Is there a correlation between the amount of lead in the system and the effects of lead?

A Well, there isn't a direct correlation between the lead and the effect, but the correlation is a population, the more lead you have in the body the more unwanted effect or poisoning you'll have in that population. So that what we're really monitoring is the more sensitive individuals that are responding in an unwanted way to the interference of lead on their body function.

Q So I understand, the blood-lead is simply measuring the amount that's present?

A That's correct.

Q And the protoporphyrin and the hemoglobin measures are measuring the actual effects of that lead?

A Yes.

[14] Q And the more lead the more likely there will be an effect?

A Yes.

Q Now, what are the dangers of lead to children? Are they any different than the dangers to adults?

A The dangers to children, the systems affected, the blood system in terms of making hemoglobin, is affected, as well as the central nervous system and the kidneys. And the difference in children is that those is much less. And the difference is that if they ingest lead they can be poisoned immediately in the sense that there is no apparent barrier between the brain and the blood, which is present in the adult, and can cause convulsions and, therefore, central nervous system damage much more severely than in adults.

The doses that it takes to do this is very much less than in adults.

Q What is this barrier that you're referring to? Would you elaborate on that a bit?

A It's the blood, there are certain things apparently during certain periods of the maturing of tissues that if you give a person, say for instance, penicillin for treating meningitis, or infection of the brain covering, the individual will not have that present in the fluids and the brain. And you say that not getting it there, [15] the blood brain barrier, the material does not pass readily from the bloodstream into the brain fluids.

Q That's called the—

A It's a blood. If you have a—you want to say there's an air lung barrier, for instance, you've got the circulation in your lung picking up oxygen, you inhale a dust, particularly doesn't enter the blood, if you inhale a gas it will enter the blood. So that the barrier of transmitting the chemical or molecule across the membrane of the blood into the fluid of the brain exists so that you don't find a concentration very great in the brain tissue or the brain fluids.

Q Now, this blood brain barrier that you referred to, does it exist in adults?

A It exists apparently in adults because of the lack of evidence of central nervous system damage in poisoned individuals who have anemia, or peripheral neuropathy problems. There's very little occurrence that the doses that we have in this country of central nervous system in the adult, and when you measure the fluids you do not find in most of the individuals that we've seen in hospitals, a significant amount of lead in the spinal fluid.

Q What about with the child, does the child have this blood brain barrier?

[16] A If a child who's under two years of age ingests just lead chip paint off of a windowsill or painted surface, a few chips in the stomach—and these sometimes

can be seen on x-ray—can cause a child to have enough lead in the central nervous system to cause convulsions, and if the dose is great enough, death.

Q How does that lead get into the central nervous system?

A It's very readily mobilized from the gut of the child into the bloodstream. Much like the inhaled soluable lead is mobilized from the deposition on the lung tissue into the blood. They're probably some enzymes and membrane transport systems that are different in children than in adults.

Q Well, it goes from the blood to where? The lead in the child.

A The blood, it goes—the blood circulating around the gut picks up the lead and then is carried to the brain in the blood.

Q Why doesn't that happen with the adult?

A Because the circulation presents the lead to the brain, but it doesn't cross into the tissue or fluid of the brain as readily as in the child.

Q When does this blood brain barrier develop in an individual?

A By the time the child is—they're more sensitive under [17] the age of two to ingesting lead and having severe poisoning from lead. By the time they're approximately five years old they've lost his sensitivity by presenting as a convulsive disorder if they're poisoned and begin to act as an adult with the same problems as the adult, and they do not mobilize as much lead from the gut, that drops off also.

Q What are the dangers of lead to an unborn fetus?

A They're the same as to the child, it is more—much more sensitive as a differentiating tissue, after the approximately second week or fourteenth day, when the fetus begins to get its blood from the mother, the central nervous system is one of the first systems that develops in the young developing child. And as in the—the child after birth, that is the most sensitive system, and that's the first to be affected.

Q What system?

A The central nervous system.

* * * *

[23] Q How do you measure the blood-lead of a fetus?

A You only can indirectly measure it through the mother's blood.

Q What's the relationship of the mother's blood-lead level to the fetus's blood-lead level?

A The blood-lead level in the mother is the same as in the child. There's no apparent barrier to crossing the placenta membrane into the cord of the baby and mother's. Nutrients get across into the—supplied to the developing fetus or baby in that manner. And the same amount of lead that is presented to the placenta by the mother's [24] blood apparently is the same for children and has been measured at time of birth by taking samples of cord blood.

Q As I understood your testimony with the adult you measure not only blood-lead level, which is the amount of lead, but also the effects of lead through the protoporphyrin?

A Yes.

Q Do you take similar studies—or can you take similar studies with the fetus?

A No, the fetus has a separate circulation, and their response to a toxic is individual. And, well, you could take samples surgically, but it isn't something that you would do to retain that. There's no way to sample the child's blood except by invasion of the uterus and the amniotic sac surgically.

Q Well, if I understand you the blood-lead level of the—of the mother is—the blood-lead level of the fetus is presumed to be the same as the blood-lead level of the mother?

A It is apparently the same by studies having been done on the fetuses of animals and cord blood in mothers, it's very close to being the same.

Q Why is the protoporphyrin measure of the mother also not the same as the child's?

A Because the effect of the lead on the fetus is to a new [25] individual. And the protoporphyrin is a measure of the mother's making red blood cells, whereas the protoporphyrin that is circulating in the developing fetus is manufactured in the same way as it would be in the mother, in the tissues that are forming red blood cells. And that is the interference in the fetus in the—by lead, with making red blood cells.

Q Is it possible that the mother has a certain blood-lead level showing no effects, or minimal effects, and the fetus has that same blood-lead level showing significant effects?

A Yes.

Q Why is that?

A For the simply reason that the mother may have no measurable toxic response to the lead. And this has been documented on individual cases where the person has a child who is born with lead poisoning, and has been treated with lead, for lead poisoning at the time of birth. And the response of the child is to the lead that was presented to him, and if it's in the range of—of above that which it responds to, 30 micrograms, or 25 micrograms, then it will be a poison at the time that it was exposed.

Q If an individual woman became pregnant and then removed herself from any excessive exposure would she be able, in that way, to protect the health of her fetus from the [26] dangers of lead exposure?

A If she is—has a certain level of circulation of blood that would be of harmful level to the fetus it would not decrease to not in a—in a specific amount of time. It may take several months to decrease to a reasonable level where there may not be any risk, so there is a risk, if you have a circulating lead that is of a danger to a child, namely, leads in the range of 30 micrograms.

* * * *

[28] Q Are you familiar with the fetal protection policy that is in effect at the Battery Division?

A Yes.

Q Did you play a role in it's adoption?

A Yes.

Q What was that role?

A The emphasis to put it in affect, it was a—a concern [29] had about exposing women to lead, and have been since 1971. And the policy to protect the fetus. I had probably the push to the Division to get it done.

Q In your judgment is that—in your opinion is that policy necessary from a medical point of view to protect the health of the unborn fetus?

A Absolutely.

Q Do you believe that the biological monitoring and other measures currently in effect in the Battery Division provide sufficient protection for the health of the male employees and those female employees who are not fertile?

A Yes.

Q Now, those provisions, as I understand it, generally the fetal protection policy, would preclude, generally, a woman that is capable of bearing children from working in an area where her blood-leads are likely to rise above 30?

A That's correct.

Q Why do you think that is necessary?

A For the simple reason that one, you do not always know when you're pregnant, and the other problem that we have in an average manufacturing facility is that conditions change so quickly, that [illegible] can have an overexposure which you may not dete[illegible] until it shows up in the circulating blood two to eight weeks later. So that if you [30] —if you have a major change in exposure that you're not aware of you cannot always see it or even measure it because of the circumstances.

Q Why would you find that the prior policy of allowing women to choose to work in high lead-levels unacceptable from a medical point of view?

A In my opinion it doesn't protect the child from overexposure to lead. Employees do become pregnant who have higher lead absorption than is reasonable.

Q In adults with—an individual with blood-lead levels of 50 micrograms and no other indication of lead effect, including the biological monitoring that exists in the Battery Division, is that individual—do you—is that individual safe, in your judgment?

A Yes, that individual would be safe.

Q A fetus who had a blood—whose mother's blood-lead level was 30, would that individual be safe, in your medical judgment?

A I would be concerned about the fetus.

Q Why are you willing to let adults work at 50 and the fetus at 30?

A There's no measure that we can measure and protect the unwanted effect of the lead on a central nervous system of that developing fetus. And the time you do measure those effects it's sometime after it has occurred.

[31] Q Nowhere in your testimony have you measured dangers to—or potential danger of lead to the male reproductive system. Is there any evidence that at some level or another there is danger to the male reproductive system?

A The only thing that has been studied is some effect on the mobility and the—the damage to the sperm, and this has been reported in the literature.

Q Now, the levels at which that—that damage or risk would arise for the male reproductive system, are they any less than the levels at which risk is generated for the other body systems and tissues which you testified were caused--were in danger from lead exposure?

A I don't think so. I think that the measures that we have for early problems that occur in biological systems such as enzymes or—or the effect of lead on making

red blood cells and hemoglobin in the red blood cells occurs much earlier than this. And in some individuals this is apparent at very low levels.

And the only thing on the germinal cells that has been documented is just a—the shape of it, or the—the motility of it. And it has occurred in the ranges that have been set of 40 to 50 for the adult working in lead.

Q If you had an adult employee working in lead with a blood-lead level of 49 and no indications of lead effect would [32] you feel it necessary to remove him from that environment if he indicated to you that he was about to have a family?

A If there were no other effects, no.

Q If you had a woman working in a lead environment with an exposure of 32 micrograms blood-lead would you give any direction if she indicated that she was about to have a family?

A I would, I would advise her to get out of exposure and allow her lead to decrease before she becomes pregnant.

Q You mentioned before that those studies that exist concerning the effect on the male reproductive system of lead exposure mentioned motility, is that what your testimony was?

A Motility.

Q Motility. What does that mean?

A The ability of the sperm to travel in fluid, it has an--an ability to—to propel itself with what they call a tail on the sperm and the ability of the sperm to travel through fluid is its motility.

Q Is that a temporary condition or a permanent condition?

A Well, any of the conditions that you affect the—the shape or the motility of the sperm where you overexpose is just like with the blood, if you reduce the—the effect it is a temporary effect.

Q In your medical judgment is there any reason to provide [33] greater protection or less exposure for the fertile male than for the unfertile male?

A No.

Q In your medical judgment is the danger to the male reproductive system any greater at lower levels than danger to the other systems in the adult male?

A No, I think the nervous system and probably some of the effects on the renal system is as great or greater than is on the germinal cells of the—either the adult male or female.

Q You say germinal cells, you're talking about reproductive system?

A Yes.

Q In your medical judgment is there any basis to provide greater protection to the fertile male than to the unfertile female?

A I think they're equal.

Q Why, in your medical judgment, is this the fertile female that needs the extra protection?

A The only reason for that is the sensitivity of the differentiating nervous tissue in the fetus, and we cannot protect the fetus when it's overexposed to lead from the mother's blood.

Q Going back to one point, Dr. Fishburn, on the studies that have shown some danger or effects of lead on the [34] male reproductive system, talk in terms of motility and what are the consequences of that, of decreased motility?

A Well, if anything, there was no follow-up study that you might lower the chances of the spouse becoming pregnant under those circumstances, but there's no data that I've read in the literature where the birth rate has been decreased in workers in this country as a result of lead exposure.

Q That would be a temporary condition, if at all?

A If at all.

Q It's just a matter of whether the spouse would become pregnant, not the nature of the pregnancy?

A That's correct.

Q Again, if you had a male with blood-leads in the forties, or say 50, and no other indication of lead effect based upon the other measurements used in the Battery Division, would you be concerned for the health of that individual's future offspring?

A If there was no effect I would not have any concern.

Q You're saying effect, based—

A Other measurements, I would not have any concern, no.

* * * *

[50] Q Globe Union has been in the past, hiring female employees to work in the lead areas; right?

A I have noted that to Globe Union the first time that I saw females in lead exposure in 1970—'71, and have recommended against this, since I first knew about it.

* * * *

Q You don't know of any fetal protection program prior to 1983; do you?

A Yes.

Q What was that?

A The previous physician, Dr. Bellmap, who's been with [51] Globe Union, would not have placed women in lead, and it wasn't until the standard for EEO that this became a problem.

Q The standard for what?

A Equal Employment Opportunity, and government contracts where you could not distinguish because of sex. It becomes a problem in industry who did not have a normal occupational medicine program.

Q You mean once the EEO got into the picture then females had to be employed and treated the same as males?

A Yes.

* * * *

[59] Q Now, if a male employee is exposed to lead and doesn't observe the necessary hygienic types of measures to cut down the ingestion of lead, and then he goes home, can that lead be absorbed by his wife?

A If any employee carries lead on their body or clothes home, other members of the family can ingest it or inhale it. Gets into the dust, in the environment in the home that they don't have filters on cleaning equipment to filter it out.

Q So if I understand it then, the wife of that employee has an exposure to her system and her fetuses?

A That's correct.

Q And that would be true even though that female didn't work for Globe Union?

A Yes.

* * * *

[60] A I don't know what the risk reduction would be in this [61] small population, but there has been a study recently published in the Journal of American Medical Association by Needleman, malformations of several thousand births in measuring cord blood of the newborn, and the various hospitals where they studied this in the East, and they were not workers working in lead exposure.

And the levels of the cord blood were in the range of—the highest reported I think was in the range of 30, 24 was a group, micrograms per hundred ml's of cord blood. And their report was based on malformations in several thousand, I think 5,000 plus births, so that as far as our data would be concerned in a small number of people I don't know how you would evaluate that kind of a risk.

I know that in my opinion if you were going to expose these people in a—to lead oxide dust and/or fume the conditions that we have at Keefe, there is a large risk of having problems with children.

* * * *

[63] Q Okay. Now, if the Company invests more money into eliminating the lead levels in the air they can reduce the risk to all employees; could they not?

[64] A Of course.

* * * *

[66] Q To your knowledge has there been any female employees employed in the Battery Division of Globe Union?

A I think those people who are not reproductive could work in lead exposures the same as in the adult male. They're both equally subject to the same responses of lead biologically. So that there is no distinction between the adult male and female except that when she carries the child, a fetus is then exposed to the same level of blood lead that the mother has, and the fetus is the problem and not the mother.

Q Okay. Now, were you consulted about how a determination should be made as to whether a female is or is not childbearing capability?

A I consult the patient for that information.

Q I'm talking about with Globe Union.

A I wouldn't consult Globe Union on that issue, if I'm taking a history examining a female.

Q Well, under the fetal protection policy if a woman is 60 years old, employed by Globe Union, should the fetal protection policy impact on that female employee?

A If she is ovulating I think it should impact on that employee. It's up to the employee in her own situation working with the doctor who established whether or not she is ovulating and that's pretty easily documented.

[67] Q But what if the Company just says, all women up to the—to age 65 are barred, is that a fair application of a fetal protection policy?

A Well, I don't think that it says that. I think that it says that if you can't reproduce at 30 or 60, and you document that, that's acceptable.

Q How has that been documented, to your knowledge?

A By medical records, by medical history. If I take your history and examine you you have another history that you've been working with your doctor. And you either know or do not know for a fact what's going on with your health. And if it isn't we ask for the employee to see the doctor and get some help on the knowledge of their present condition.

* * * *

[73] Q I'm asking for your opinion, in your professional judgment, has implementation of the fetal protection policy [74] reduced the risk of danger to the fetus—unborn fetus of female employees?

A Yes.

Q Where the mother has blood-leads greater than 30 is the risk to the—in your opinion—is the risk to the fetus significant?

A It's significant, yes.

* * * *

[77] Q Now, if I understand your concern on the biological standard was that you don't believe you can measure the health of an individual solely on the basis of the single blood-lead level?

A That's one. And besides, if you wait to measure an exposure effect on an individual this is not a preventive program. The nature of industrial hygiene is controlling of exposure. The nature of safety is controlling the risk of injury. And if you do that then what the occupational health program is for is the medical monitoring, says, yes, you did the job and people are healthy. That's the basis of preventive occupational medicine.

Q If your concern—well, let me go on back on that. You're saying that just using biological monitoring is too late?

A You've already been exposed if you measure in the blood. And if it's carbon monoxide and you've got too much you're dead.

Q If you have this concern of using—even using biological standards of a single blood-lead level why is that the criteria that is used for the fetal protection policy?

A Because there you're protecting a specific system, namely, [78] the central nervous system, of a developing child, or after birth the young child, which is directly affected by the poison. And if you increase the level of exposure to that system you're going to have a certain number of people affected later in life, or immediately, which is learning and behavioral difficulty.

And that is the critical issue in terms of childhood lead poisoning, protecting them from being exposed, and in the cases of the general environment, protecting the families in the sense of the fetus from the exposures.

Q And the blood-lead level in that instance is directly connected with the damage as opposed to the other issues what you were talking about in your testimony?

A Because there is apparently no barrier to the lead entering the tissues or the fluids of the brain, particularly up until about five years of age. And it drops off from two to five, there is less difficulty. But from two to birth and before from the fetus it is particularly sensitive to the effect—adverse effect of lead, and there is no—whatever is is in the blood of the mother or whatever is in the blood of the child, affects the brain.

Q Directly?

A Directly.

[79] Q If I understand correctly, in an adult the blood-lead level, because of this blood brain barrier, will have a different impact on different individuals?

A That's correct.

Q Or may not have any impact on them?

A It may not have any impact on them.

Q And in the child this barrier doesn't exist between the blood and the brain?

A That's correct.

Q Now, even if you wanted to, on a regular basis, use measures in the fetus beyond the blood-lead level, can

you, on a routine basis, measure the ZPP, or the zinc protoporphyrin of the fetus?

A No.

Q Can you do a physical examination of the fetus?

A No.

Q Can you measure hemoglobin in the fetus?

A The only way you can do any measurements on the fetus is by invading—by invading the uterus and the amniotic sac, it's a surgical procedure.

Q Without using surgery could you perform any of the measurements that you do on the adult employee at the Company other than the measurement of the blood-lead level of the fetus?

A That's all we could do.

[80] Q That's the only criterian you have available?

A Yes.

* * * *

[81] Q Now, just so the record is clear, on the adult of the employee, other than the blood-lead what actual measures do you take, or how do you evaluate the health of the employee concerning lead, other than the blood-lead?

A We monitor the effect of lead on heme-synthesis by doing protoporphyrines.

Q Is that what's worded as ZPP?

[82] A That's ZPP. If we do the ZPP on the hemato-flourometer in the plant and we're not satisfied we'll ask for a wet chemical procedure called free erythrocyte from the laboratory. And it's a doublecheck on our levels of protoporphyrin. We also do CBC, a complete blood count involving all the cellular elements of the blood and biochemistries, which monitor the functions of other organ functions, such as kidney and liver function, and the biochemistry, really, of the blood.

Q What else do you do in evaluating the health of the employee with respect to lead exposure?

A We look at the individual from an examination point of view, and the history—medical history, as well

as we look at the exposure history of that employee. On occasion if there's some question we may go out and even evaluate the job.

* * * *

[86] Q You were asked questions concerning the possibility of an employee carrying lead home and affecting the family. In what way could lead be carried home?

A If they do not clean and shower, if they're in a dusty or dirty area if they do not change their clothes, if they do not change their shoes. They can carry lead home in their clothing and on their shoes and on their body.

Q Now, if—are there measures in place at the Keefe plant to prevent that from happening?

A Yes.

Q What type of measures?

A They have clothing and shoes and shower facilities. They have—if you have long hair you can get nets for your hair, in addition to the showers and gloves and the whole gamut of protective clothing and protective equipment so that you can leave the lead in the plant.

Q If an employee does all of these things and takes no lead home on his clothes, on his body, in his hair, or on her clothes, on her body, on her hair, but had been exposed to lead so that that individual has relatively high blood-lead levels, is there any direct risk to the rest of the family?

[87] A No.

Q When you're talking about carrying lead home you're talking about carrying it on the surface?

A On the surface, yes.

* * * *

[91] Q You've touched on something there. If I understand it, you would go more to the individual now, even if he had—was in an air exposure of a hundred, that wouldn't necessarily disqualify him from anything, he may not show any effects of even high blood-lead levels?

A That's correct.

Q And also, even if that certain individual had blood-lead levels above 50 he may not even be affected by that because of other characteristics of that individual?

A That's correct.

Q Now, the fetal protection policy just is a flat policy applicable to all that's not consistent, is it, with the individual approach?

A No, it's consistent with the individual approach to the fetus, where we know that—that at a specific age and up until that age you have brain damage if you're exposed to a blood-lead of a certain level, or you have the absorption of that level into the tissues. And above this the children are affected by central nervous system damage, and that's a developed mental thing and it has nothing to do with the adult lead poisonins situation.

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[EXCERPTS OF CHISOLM DEPOSITION]

(Second Aff. of Jaspan, Ex. A)

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[15] whatever that level may be at any given time, the real impact of, say, a woman of child bearing capability who has been exposed to a certain level of lead is in some kind of adverse affect on her physical or mental capacity, is it not?

A The affect I think is on the fetus. I don't know that there is any real effect on the woman at that level, but it is on the unborn child.

Q At the level of 30 micrograms?

A Well, the risk increases. What you get is a dose dependent increasing frequency of unwanted effects. It is an affect on the fetus that we are concerned about, primarily on the latter growth spurt of the brain, which occurs in the latter half of the last trimester of pregnancy. That is what the concern is about.

Q I see. In evaluating this effect, you would look to see, for a given level of exposure of the mother to lead, you would look to see—to measure its effect, you would look to see certain aspects or certain affects on the fetus or on the offspring after it was born to determine what the effects were. What effects would you be seeing in these offspring?

A Well, I think that the recent paper by Bellinger is very much to the point, and they divided the women into three [16] groups: those who had mean blood leads of less than—those who had blood leads less than 3 micrograms per decaliter, 6 to 7 micrograms per decaliter, and equal to or greater than 10 micrograms per decaliter. And what they have used, what they have used is the Bailey mentla developmental index. That I would say is the most widely used scale of infant development for the first two years of life. Other scales come along later.

What we have found, what in effect the group in Cincinnati has also found is that as the blood lead concen-

tration increases, the cognitive development of the infant field is delayed. The psychomotor level index, which is the time at which the baby sits, stands, walks, and so forth, that is not affected, but rather it is the cognitive development. And they show in this study that there is a highly significant relationship between the cord blood test, that's the biggest blood lead at the time of birth, and his mental developmental index at six and twelve months of age. And that it is not related to the current blood lead. That is, the blood lead taken at six months of age. In fact, the blood leads that an infant has at birth are not correlated at all with subsequent blood lead levels. And I think that applies to this Cincinnati [17] study.

They carried this out, now, to two years of age, and they still find, although not at 18 months, they still find a significant correlation relationship between the mental developmental index of 24 months of age and the cord blood lead, and these—the analysis has been adjusted statistically to account for compounding factors.

I would consider this highly significant. Whether we are dealing with a delay in development or whether these are permanent effects, we will probably have to wait until these children are six to eight years of age.

Q At this point, at least—

A But it is perfectly clear that there is at least a delay. And from these data, you obviously can't tell whether it is permanet. There are some animal data that suggests that you can get a dealy. There are other animal data, particularly monkeys, that would suggest that very early low-level lead exposure is in fact associated with permanent impairment, really in learning ability and in responding under stress.

Q What animal study is it that involves the monkeys?

A The ones I am thinking about are those by Deborah Brice. They are published in Toxicology, Applied Pharmacology. [18] But she has been following monkeys out to eight years of blood that were dosed in the first 200 days of life, and I would say that is a fairly recent

publication, but they suggested that the effects may be permanent.

Q Are these at levels comparable to the levels we are talking about?

A Well, the group I am thinking of are infant monkeys that never had blood leads above 25 micrograms per decaliter. But I think these human data are very disturbing; it is not only the Bellinger study in Boston, but also studies in Cincinnati—I presume you talked to Dr. Hammond about that, quite recently in relation to this matter. And the studies are quite, quite consistent.

There is also an effect apparently on birth weight and length of gestation, an inverse relationship. As the blood lead level goes higher, the lower the birth weight, the shorter the gestation time.

Q Is there any explanation offered in any of these studies as to how the lead exposure operates to cause a lower birth weight?

A I don't know of specific studies, but lead certainly does interfere with—it does bind the DNA, it can affect [19] that; it affects energy, all the interest in impairment of hemosynthesis is related to energy production, and in past experiments in the brain, you can show that oxydative phosphorylation, which is efficiency of energy use, is impaired.

Lead binds to and is retained by an infant brain, that is the difference between an infant brain and an adult brain.

So that the basic level mechanisms are known that would explain this.

And I think it is reasonable in relation to the build-up of lead in the fetus. There is only one study that I know of on that issue, but abortuses, stillbirths, miscarriages have been analyzed for lead by Barltrop. They show that the lead builds up really in the last trimester of pregnancy, so that the tissues of stillborns who are at term are comparable to those found in the nonpregnant adult female. The real build-up comes toward the end.

Q Toward the end?

A The latter half of the pregnancy.

Q You emphasize a certain concern for exposure, lead exposure, in the latter half of pregnancy. Does that suggest that a woman who becomes pregnant, who maybe has 25 or 30 [20] microgram blood lead level at the time that she first becomes pregnant but is removed from that lead environment immediately and moved into an environment with a blood lead—I mean, an air lead level or an ambient lead level where the population is exposed to, which is much less lower than the industrial levels—I am not sure what that would be—maybe 9 to 10 micrograms per cubic meter range, something like that—would she then be expecting to have the same kind of adverse effects on her offspring as you have just described?

A Well, I think the answer to that is a little complicated. In the first place, it depends upon how long she has been working, because lead builds up not only in the blood and soft tissues, but it is stored in bones. And it is sort of a safety valve for us, if you will, in an effort to keep our soft tissue levels low and uniform.

Well, even when someone stops exposure, while you may be getting a lower input from the air, food, or whatever, you are going to have a turnover of lead in bone and you are going to have lead feeding back out from the bone.

The pertinent experiments on this are really those of Dr. Kehoe a number of years ago, who followed men—didn't follow women, but followed men by feeding them extra [21] lead. He then plotted how long it took for their blood leads to go down. And the rule of thumb was that it took at least twice as long for it to go down as it did for it to go up.

A better estimate would be two to three times as long.

So if this hypothetical woman has been employed for any length of time, her blood lead is not going to go down that fast. Not only that, but there is a real concern—a woman who is pregnant is at risk in decalcifying her bone. There is also real concern for mobilizing the lead in the bone.

So I don't think that you can say if she stops shortly, well, promptly, she would be out of the woods.

There is a study, a report in this paper by Ronald Lane about an episode that occurred in the Second World War in Britain, and one of the points he made was that they removed the women from work as soon as it was known they were pregnant, and one—he doesn't say specifically, but one presumes that two, three, or four months, something of that order—even so, there are an excessive number of stillbirths.

Now, these were women, the didn't do any blood leads on the women, didn't even do urine leads. But if you take the air leads and the urine leads on the men, one could estimate that they probably had blood leads of, say, 50, 60, or 70 [22] micrograms percent.

So the point is here—now, they had much higher levels than you are talking about, but it takes awhile for it to disappear, and there is no drug that I know of, no chelating agent that could be given to accelerate this that would be safe.

The most common drug used is calcium disodium EDTA. This drug is clearly teratogenic. It is teratogenic because it removes a lot of zinc. That has been done in animals.

If you give zinc in EDTA, you don't get any abnormal offspring in the dogs I am thinking about. If you give calcium EDTA, you do get congenital malformations throughout the pregnancy.

So there would be no safe way to treat the person.

* * * *

[25] Q Right. Given that there is a dose-response relationship, if we hypothesize a woman who has previously not been employed in any kind of increased lead environment but, say, was at the threshold community median level, and subsequently became employed in an area in which there were higher levels of lead in the air, and she worked there for, let's assume, a period of two months and her blood lead level increased to let's take, for example, 25 micrograms per decaliter of lead, based

upon the information and the studies that suggest that it takes two to three times as long to come down, for the blood level to reduce itself to its former level, would you still anticipate that had that person become pregnant at the time that they had achieved this 25 microgram blood lead level, that they would [26] have offspring with measurable abnormalities, central nervous system damage?

A Well, in the first place, we are dealing with a risk factor.

Q I see.

A We really can't say about individuals.

In the second place, the rate at which it falls may depend upon our past exposure.

Q I understand.

A And remember that the general population exposures in the past and fairly recent past have been higher than they are now. All of that is going to relate to the rate at which her blood lead declines.

But if you assume that she conceived, went to work for two months and went up to a blood level of 25, and then it is going to be four to six months she will be practically through her pregnancy.

So, I don't think any specific answer can be given to your question. I would be rather doubtful, though, it might be back down below 10 by the onset of the third trimester pregnancy.

I really couldn't answer that question. It is a [27] hypothetical question.

Q I understand.

Could you say that it is possible that there would be no observable damage to the central nervous system under that set of circumstances we just described?

A What do you mean by "observable"?

Q You earlier described some measurable adverse affect on the central nervous system as a result of fetal exposure.

A I wouldn't anticipate any, obviously, anatomical malformations whatsoever, although I know that Needleman has reported minor malformations of no consequence.

What we are worried about are very subtle things, the ability to really affect learning ability. And so far as impairing the child's progress they really aren't evident until he gets into school. He discovers that he can't remember, that his brain cannot pay attention, what our psychologists here called deficits in auditory processing, which is a fancy way of saying they can't understand what they hear, can't process it, and use it effectively. And those things will impair a child perhaps toward the end of the first grade, particularly in the second grade.

Q Given the example that we just talked about, are you [28] saying that you can't predict whether there will be an adverse affect or not?

A Well, I would have to put it this way I think, the risk that there might be an adverse affect would be greater than if a blood lead had never been above 10.

Q Could you also say, based on what we just talked about, that the adverse affect of the offspring born to that woman who had only been exposed for two months, compared to the offspring of a woman who had been exposed throughout her pregnancy, through the full nine months, would in fact be—the risk of adverse damage to the central nervous system would be lower for the person who had only been exposed to two months as opposed to that person that had been exposed for the full nine months?

A Well, in theory, I guess the risk would be less, but I don't see how you would ever say about individuals.

You would have to have very large groups, and you might find that the frequency was somewhat less under those circumstances.

Q Doctor, in your review of the literature on the toxicology and based on your own experiences, is there any suggestion that the exposure of men can alter the genetic [29] characteristics of their sperm, such that a resulting fertilization of an ovum by that sperm could result in a child with some observable abnormality?

A I don't think that there is any evidence to support that.

Q In your opinion is it possible that a man exposed to lead who acquires, let's say, a 30 to 40 microgram blood lead level could have an altered genetic characteristic of his sperm?

A I wouldn't know of any evidence in favor of that. Any animal data is generally at much higher doses that are not relevant to the human situation, and furthermore if you go back 100 years or so ago, one of the things that I think stands out fairly clearly in the old literature is that lead is not a teratogen. In other words, they never had anatomical malformations; those were never recognized. Increased rates of miscarriage and stillbirth were reported, and that, in fact, is what led a British Royal Commission in 1910 to recommend that henceforth women never be employed in the lead trades. And that was enforced by law in some countries.

Q You just made an observation that the animal studies which might suggest that there might be some genetically [30] altered—

A I think those were mostly in vitro studies, too.

I don't recall offhand any that—well, it has never really been possible to produce malformations in animals by oral feeding. The only one who has ever done it, or the only time it has ever been done is at very large doses by injection. And teratologists really would argue whether you are dealing with something genetic or whether you are simply dealing with direct damage or toxicity due to the overwhelming dose you have given him.

I say Goyer and Stowe did feed animals, but they fed them again quite high doses, and they could find that the offspring were smaller, that sort of thing, but again I don't know of any malformations. Any anatomical malformations I am talking about.

Q Certainly. Let me just ask you, what is your reason for saying that the animal studies do not have any relevancy to human circumstances?

A Well, now, I am not a reproductive biologist, but reproduction in rodents in particular is quite a different

proposition than that in man, for example. I don't think they are directly transferrable.

[31] Many of these studies have been done again at very high doses and lead is—actually not studies have been done, again, at very high doses, and lead is actually not studies to determine dose-response relationships as far as lead is concerned but to give a high enough dose to produce an effect, so that they could study the effect scientifically. In other words, the lead is an experimental tool on a number of these studies.

Q Does that mean that at least according to your understanding, that the affect of lead on the reproductive systems of animals, rats, and some other studies, is not transferrable to the information regarding humans?

A Not directly. Most of the animal studies are mechanistic. What you look for, they are trying to study mechanisms. And then if you will study rodents, you would go to another type of animal to see if the same mechanism is there.

But I can't say that they have any application to the very low level exposures. I think that the more human exposure data you have, the better off you are.

Q If I understand you correctly, then, you are saying that the way in which lead affects animals' reproductive systems, the mechanics of that affect are so different from the [32] mechanics of its affects on humans—

A From my reading—

Q —that you simply can't transfer the results or the conclusions from animals to humans?

A Directly.

Q Can you do it indirectly?

A Well, I think you would look, if you discover some mechanisms in animals, you might look—I think a reproductive biologist would look to see if you can find some kind of evidence of the same thing in humans. But it is certainly my understanding that the situation is different.

As I say, I am not a reproductive biologist, and not having done a study.

Q I understand.

Based upon your understanding, then, would you conclude that there is not evidence of spontaneous abortions or stillbirths where women, unexposed women have been made pregnant by exposed men?

A I don't think there is any evidence that exposure of the male per se has any affect on the offspring. A number of the older studies—we are dealing with cottage industries where both men and women are exposed, we also know that they [33] may have brought home lead containing dust and so exposed their wives in the home.

But I don't think we have any studies where it is male exposure per se that results in this, that results in ill effects on the offspring. And I think that all of the data would indicate that the women—you may have both exposed, quite true, but the women have to be exposed. Because, after all, the fetus is in the woman's body. And it is the transfer of the lead through her body across the placenta to the fetus that is what is having the direct effect.

* * * *

[37] In workers, we certainly are aware anecdotally of cases where children do develop high blood lead levels in relation to workmen bringing lead dust home.

There is a report by Baker in the New England Journal of Medicine—I think that might be almost ten years ago—in Memphis, Tennessee, where the workers in a battery plant were bringing dust home.

I have run into occasional cases in practice, there are some studies reported by, let's see, Dolcourt. They are mainly reported by Schroeder out of Chapel Hill. There is a mixture, but really what got them started was the study of children, screening of children who were found to have increased blood lead concentrations and further examination showed that their mothers worked in a battery plant and brought the dust home. So there are—and I think there are other episodes of such things, but I don't know of any, other than the Schroeder study,

any study which has concentrated on this group; that is, the children of workers who brought lead dust into the [38] home.

Q If you can recall—

A And they are not large groups, so they don't have the statistical power of larger groups, such as those being studied here in Cincinnati and Boston.

Q What were the observed blood leads in the children that were measured in that study if you can recall?

A I think in the Baker study, in the Baker study there were three or four children who were symptomatic and had blood leads in excess of 80, and the report said that they found no other reason than the dust was brought home.

* * * *

[40] Q From your testimony here today, it can be concluded that in your opinion, lead does not have an adverse effect on the genetic characteristics of sperm?

A I don't think, in the human race there is no evidence for that, and there is a lot of experience up to—in the second half of the 19th century, anatomical malformations were not found. It seems to fit quite well with the work of Voltrop which indicates the transfer of lead across the placenta is something that occurs later.

If it were getting to the embryo during the period of organic genesis, you would expect, in significant quantities you would expect some anatomical malformations and the experience does not show anything.

Q You have earlier indicated that in your opinion, that is not teratogenic with respect to humans; is that correct?

A I am using it in a classical term.

Q When you say classical term, you mean—

[41] A Well, I mean anatomical, gross anatomical malformations.

Now, again, I am aware—

Q Physical observable?

A Yes. I mean, you are going to get congenital cardiac malformations or something that will be ultimately diagnosable.

Now, I am aware of these minor things that Needleman reported, perhaps the most common of which is inguinal hernias. But that can be looked at simply as a delay in the latter development. In other words, you are not talking about a malformed organ; you are talking about a development that is slower. The inguinal canal should be sealed up at birth. If it is not, it ought to be sealed up shortly thereafter. So I think he called that a mild malformation. I don't know that it really is.

Just like umbilical hernias can be delays in the closure of the umbilical ring. Many of those umbilical hernias in babies, they will heal by themselves. You don't have to do anything with them. If they are big, you may have to. But I am talking about significant anatomical malformations.

* * * *

[47] In 1985, the CDC said in order to provide a margin [48] of safety, they would lower the level to 25. And I am saying now that in light of these newer data, perhaps these procedures need to be reevaluated, reconsidered.

I am saying that 30 at the time it was issued would be generally—would represent the general consensus, but as we get newer information, we may have to modify this. But, on the other hand, I am not in industry, but I wouldn't see how you could try and maintain blood leads at 10 or less and be occupation exposed, which seems to me to say they shouldn't be occupied in the lead trade.

* * * *

[49] Q Doctor, have you had occasion or opportunity to actually read through the deposition of Anthony Scialli?

A I read quickly through this last night, around midnight.

Q Can you recall at this point any of the conclusions or testimony of Dr. Scialli?

A I think he is the one who was testifying to the effect that you couldn't make direct transfers from animal experiments.

* * * *

Now, I don't know whether he's the one that said that he thought that there might be some effects early in pregnancy. I would have to disagree with that.

* * * *

Q Excuse me. With respect to his conclusion that you [50] can't make a direct transfer of animal studies to human situations—

A Right.

Q —are you in agreement with that conclusion?

A Yes, and I think there probably is a consensus; I think there are other people who would agree with that. But I also told you that I am not a reproductive biologist.

* * * *

[51] A This is an abstract from a presentation by David Bellinger at the International Conference on Heavy Metals in the Environment, in Athens, Greece, in September 1985. And [52] it is entitled "A longitudinal study of the developmental toxicity of low level lead exposure in the prenatal and early postnatal years." And it carries this up to two years of age.

What they are showing—in other words, it carries this paper that was recently published covering the first year of life to two years of life, and it would indicate that a significant effect on the Bailey mental developmental index related to the cord blood lead obtained at birth on the infant; that that is still showing a significant affect out to two years of age. So it is an extension of this other study that I mentioned.

And thes, as he says, "Cord blood lead greater than 10 micrograms per decaliter but less than 25 micrograms per decaliter were consistently associated with

less favorable early mental development in our sample of low-risk infants."

So it appears to say that the affects that they observed in the first year of life are continuing on into the second year of life. And again, I think the important point about this is that these children would not be considered to be overexposed postnatally by current standards.

* * * *

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

AFFIDAVIT OF ANTHONY R. SCIALLI, M.D.

DISTRICT OF COLUMBIA) SS.

ANTHONY R. SCIALLI, M.D., being first duly sworn, on oath, deposes and states as follows:

1. I am a physician licensed to practice in the States of Maryland, California and Virginia and in the District of Columbia. I received my medical degree in 1975 from Albany Medical College. Attached hereto and incorporated by reference as Exhibit A is my curriculum vitae which lists, among other things, my educational background, professional experience, professional appointments and memberships, as well as a bibliography of my professional publications.

2. I am engaged in the clinical practice of obstetrics and gynecology.

3. In addition to my clinical practice, I am also Director of the Reproductive Toxicology Center located in Washington, D.C. The Center serves as a source of information on the potential reproductive toxicity of environmental and physical agents. I have done substantial research in the field of the toxic effects of lead exposure on humans, with particular emphasis on the effects of lead on reproductive health.

4. There is an ever growing body of medical literature which establishes that the central nervous systems of

young children can be permanently adversely affected by blood lead levels in excess of 25 micrograms per deciliter of whole blood. One of the leading reports in this area is the January 1985 Statement by the Centers for Disease Control of the U.S. Department of Health and Human Services, "Preventing Lead Poisoning in Young Children", which is attached hereto and incorporated by reference as Exhibit B. The Statement concludes that young children are considered to be lead intoxicated if their blood lead levels reach 25 micrograms.

5. In my medical opinion, because of the extremely rapid development of the central nervous system during gestation, the fetus may be even more sensitive to the toxic effects of lead than the young child. While the exact level at which there is no effect on the fetus is unknown, it can be stated with a high degree of certainty, based on current medical knowledge, that 25 micrograms is the highest possible acceptable level.

6. During pregnancy the mother's blood lead passes through the placenta to the fetus. Therefore, the fetus' blood lead level is approximately the same as that of the mother. Measuring the blood lead level of the mother is the only clinically acceptable method to estimate the blood lead of the fetus.

7. The potential damage to the central nervous system of the fetus from lead exposure includes intellectual and motor retardation, behavioral abnormalities and deficiencies in learning abilities. It is my medical opinion that such damage may be permanent.

8. There are no studies that show that the exposure of the adult male to blood lead levels of up to 50 micrograms will result in any abnormality in the offspring. The medical studies generally conclude that the exposure of men to toxic substances analogous to lead does not result in an increase in adverse outcome in offspring. Further, the available medical evidence establishes that lead does not cause any change in the sperm that would

be expected to be transmitted to the offspring and result in an abnormality in the offspring. In my opinion, based on current medical knowledge, a man with a blood lead level of 50 micrograms is not expected to have an increased risk of fathering a child with any type of abnormality caused by his exposure to lead.

9. There are some studies that have been performed on rodents which show that lead exposure may cause reproductive toxicity in rodents. However, these studies cannot be extrapolated to humans. The reproductive system of the rodent, in terms of transmissible changes in offspring due to exposure to toxic substances, is simply not analogous to the human reproductive system, male or female. This is demonstrated by the fact that there are a large number of compounds other than lead which cause reproductive toxicity in rodents, but not in humans. A specific example is the drug Thalidomide which was used in the 1960's to treat pregnant women. This drug was given to mice and rats and did not cause any birth defects; however, the drug caused major limb defects in human offspring. Further, the tests in rodents which have concluded that lead caused chromosomal damage deal mainly with things such as a change in the shape of the sperm, which in rodents is a genetic factor. However, this cannot be extrapolated to humans because there is no evidence that sperm shape in humans is determined in the same way; rather, it is a particular feature of the rodent that sperm shape is determined by genetic factors.

10. Lead toxicity in an adult is, to a large extent, reversible or likely to be reversible. Further, lead exposure of 30 to 50 micrograms is not likely to produce any significant adverse effects in adults; however, at these levels there is a substantial risk of irreversible neurological damage to the fetus

11. Because of the special susceptibility of the fetus to lead and the fact that the fetus is exposed to the

same blood lead levels as the mother, it is my medical opinion that all women of reproductive potential should be removed from work areas where their blood lead levels may rise above the average level of nonexposed individuals in the community. I would include in this prohibition all women who have ovarian function or who have a genital tract which is open, whether or not they intend to bear children at a future date. This would include women who have no intention of bearing children, but who are still capable of bearing children, because there is no foolproof method of birth control and, therefore, there are many unplanned pregnancies. I would exclude from this medical prohibition only women who are menopausal or who have had a tubal ligation or hysterectomy.

12. In my opinion removing a woman from lead exposure only after she actually becomes pregnant is a medically unacceptable means of attempting to protect the fetus from the adverse effects of the mother's elevated blood lead. If a person has been exposed to lead for any length of time, the lead could remain in the body for months or years after removal from exposure. Therefore, during the nine months of gestation the fetus will be exposed to harmful levels of lead from the mother's blood despite removal of the mother, thus creating a significant risk that the child will be born with a neurologic injury.

13. This Affidavit is made and submitted in support of the Motion for Summary Judgment of Defendant Johnson Controls, Inc.

Dated this 31st day of July, 1986.

[Signatures Omitted in Printing]

* * * *

A STATEMENT BY THE CENTERS FOR DISEASE CONTROL—JANUARY 1985

(Scialli Aff., Ex. B)

PREVENTING LEAD POISONING IN YOUNG CHILDREN

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control

[7]

OCCUPATIONAL SOURCES

Lead dust can cling to the skin, hair, shoes, clothing, and vehicles of workers, and lead can be carried from workplace to home in this way. In a study in Memphis, Tennessee, when a parent worked with lead, the amount of lead in the children's blood correlated with the concentration of lead in dust in their homes (Baker, Folland et al., 1977). Of 91 children tested, 38 (41.8%) had blood lead levels of 30 μg/dl or more, and 10 either had blood lead levels of 80 μg/dl or more or EP levels above 190 μg/dl.

Strict compliance with Occupational Safety and Health Administration (OSHA) standards is quite effective in decreasing this type of exposure. However, many occupational exposures to lead are not covered by the OSHA standards. Companies with fewer than 10 employees (cottage industries, "hobby" production of pottery and stained glasswork, and home manufacturing of bullets and fishing sinkers) are excluded from OSHA standards.

The OSHA standard for lead workers is a blood lead level of 40 μg/dl. In a pregnant woman, lead crosses the placenta, and lead concentrations in umbilical cord blood are nearly equal to those in maternal blood (Barltrop, 1966). Since the growing brain of the fetus is likely to be at least as sensitive to the neurologic effects of lead as

the brain of a young child, umbilical cord blood levels should be at least below 25 μg/dl. Therefore, the OSHA standard is probably not sufficiently strict to protect the fetus. Further study is needed to define acceptable lead levels among women of childbearing age.

* * * *

[20]

OCCUPATIONAL

Ideally, engineering features should prevent workers from being exposed to lead dust and vapors. When workers are exposed, compliance with Occupational Safety and Health Administration (OSHA) regulations appears to be effective in protecting them and in preventing them from transporting lead home to children. Under the OSHA lead standard, factories that use lead must provide workers with facilities for showering and changing [21] clothes and shoes before going home from work. This standard now applies only to industries covered by OSHA regulations. For the protection of children, it should be extended to all industries that use lead. The prevention of lead exposure to the fetus needs special emphasis. Women of childbearing age should be excluded from working at jobs where significant lead exposure occurs.

* * * *

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

STATE OF CALIFORNIA)
) ss.
COUNTY OF ALAMEDA)

AFFIDAVIT OF M. DONALD WHORTON, M.D., M.P.H.

M. DONALD WHORTON, M.D., M.P.H., being first duly sworn, on oath, deposes and states as follows:

1. I am a physician licensed to practice medicine in the State of California. I received my medical degree in 1968 from the University of New Mexico and my Masters of Public Health in environmental medicine in 1973 from Johns Hopkins University School of Hygiene and Public Health. Attached hereto and incorporated by reference as Exhibit A is my curriculum vitae which lists, among other things, my educational and professional background, board certifications, and professional affiliations and activities. It also includes a list of my professional publications.

2. I am the Senior Occupational Physician/Epidemiologist at Environmental Health Associates, Inc. located in Oakland, California. Environmental Health Associates, Inc. does research in various areas of occupational and environmental health and is a primary medical consultant for a number of companies. This research and consultation includes the field of the toxic effects of lead on adults, children and the fetus.

3. I have been an Associate Clinical Professor of Occupational medicine at the University of California School of Public Health located in Berkeley, California, since 1979.

4. Attached hereto and incorporated by reference as Exhibit B is a bibliography of some of the medical literature I have reviewed regarding the toxic effects of lead.

5. Attached hereto and incorporated by reference as Exhibit C is a written version of a presentation on Lead and Fertility that I gave in May 1985, at a medical conference held at Duke University.

6. Based on my work and review of the literature in the area of toxic effects of lead, it is my medical opinion that the current OSHA lead standard of 50 micrograms per deciliter of whole blood should generally protect adults of either sex from significant adverse effects in the various adult systems.

7. In approximately 1981, Dr. Andrew Wyrobek and I, as co-investigators, completed a study, funded by the Environmental Protection Agency, in which we evaluated the semen quality of male workers engaged in the production of batteries in Pennsylvania and who had, accordingly, been exposed to lead. The average blood lead level of these male workers was approximately 43 micrograms. In this study we compared the quality of the semen of the lead exposed workers to a control group of non-exposed males. We discovered no changes in semen quality in the group of lead exposed workers. I have also reviewed the other pertinent articles relating to the effects of lead on human males, especially on the function of the testes. Based upon the current medical evidence, it is my opinion that there does not appear to be significant functional harm to the reproductive system of male workers when the current OSHA lead standard of 50 micrograms is followed.

8. Very recent medical studies, that have come out of Boston and Cincinnati in the last year or two, are showing injury to the central nervous system as a result of fetal exposure to blood lead levels as low as 10 micrograms. These studies measured the blood lead levels of groups of infants at birth and then compared the subsequent neuro-behavioral development of these children. The studies show a direct correlation between blood lead levels and maturation levels of the infants. They suggest that even relatively low levels of lead exposure to the fetus can cause damage to the higher brain function resulting in decreased neuro-behavioral development in the child. There is no evidence of comparable harm to adults at this level of exposure. Further, while it is too early to determine conclusively from the available studies whether the damage to the central nervous system is permanent, based on current medical evidence it is my medical opinion that there will most probably be some permanent damage.

9. It is my medical opinion that the central nervous system of the developing fetus, and not the reproductive or other systems of the male or female workers, is at greatest risk from the toxic effects of lead. Because the fetus is exposed to blood lead levels similar to that in the maternal blood during at least the majority of pregnancy, it is my medical opinion that any woman who plans to have or may have children at any time in the future should not work in a job with lead exposure.

10. This affidavit is made and submitted in support of the Motion for Summary Judgment of Defendant Johnson Controls, Inc., in the above-entitled action.

Dated this 11 day of August, 1986.

[Signatures Omitted in Printing]

* * * *

(Whorton Aff., Ex. C)

LEAD AND FERTILITY

by Dr. Donald Whorton

Environmental Health Associates

Oakland, California

This paper is a brief review of the effects of lead on reproduction, primarily in humans, for both males and females. The potential occupational reproductive effects of lead became a regulatory issue in the United States when the Occupational Safety and Health Administration (OSHA) proposed a new lead exposure standard in the mid 1970's. In the proposed standard, OSHA attempted to equate the adult male and female reproductive risks from lead. This attempt at equalization of risks caused considerable controversy from both scientific and policy viewpoints. Other reports in this meeting have discussed scientific and policy issues of lead exposures, primarily for young children.

Historically, much of what is known about the effects of lead on human reproduction comes from observations made around the turn of the twentieth century. Women suffering from clinical lead poisoning have been shown to have decreased fertility, increased rate of spontaneous abortions and an increased rate of stillbirths. Lead has been used as an abortifacient since antiquity. In addition, various lead salts have been used as spermicidal agents. Thus, lead and adverse reproduction effects on women have been known for a long time. (1,2)

Results of animal studies have shown lead to have adverse reproductive effects in numerous species for both sexes. The following are representative of these effects in female animals. In female Rhesus monkeys, lead can cause inhibition of follicular growth, failure of ovulation and proliferation of ovarian connective tissue. These changes produce a decrease in fertility of the Rhesus

monkey. In hens, delay in sexual maturation, decreased number of eggs laid; and decrease in functional fertility have been shown to occur from lead exposures. In ewes, lead produces a decrease in rate of lambing and an increase in rate of spontaneous abortions. Among studies of male animals, the following are representative. In rats, lead has been shown to produce impotence, prostatic hypertrophy and a decrease in testicular weight. These effects would affect the male rat's ability to reproduce. In the mouse, decrease in fertility has been shown. (3) In the mouse sperm morphology test, lead acetate produces an increase in abnormal sperm heads. Additionally, this abnormal sperm morphology pattern can be transmitted to the F_2 generation. (4)

Is lead a teratogen? Before answering the question, some definitional clarity would be useful. Classically, a a teratogen is an agent which produces a structural abnormality or change in the embryo/fetus. These structural changes are generally classified as major or minor. Most birth defect reporting originates from the initial examination of the newborn within the first three days of extra-uterine life and recorded on the birth certificate. Most birth defect entries tend to be major effects, not minor ones. However, during the past decade or so, the concept of functional birth defect has been well accepted. This type of effect was observed in children born to mothers who were heroin addicts. These children had considerable emotional and learning disabilities. Many of these problems were not recognized until the child was 2+ years old or until the child started school.

For most teratogenic agents, there is a specific, finite time period in which the embryo/fetus is most susceptible or susceptible at all. During the pre-differentiation period, which occurs from conception day 1 to conception day 14 (the first two weeks of conception in humans), the conceptus is not susceptible to the effects of teratogenic agents. In the early period of differentiation, (con-

ception week three through conception week eight), the embryo is most susceptible to teratogenesis from teratogenic agents. Then, with the period of advanced organogenesis until birth, there tends to be an increase in resistance to the effects of teratogenic agents. (5)

For the central nervous system, the period of greatest susceptibility to teratogenic effects is conception week three through week six; however, the central nervous system remains vulnerable throughout all of pregnancy. The pathologic effects of lead on the central nervous system of children under age 5 is well recognized and accepted: encephalopathy, mental retardation, etc. One would expect similar adverse central nervous system effects to occur in the fetus with sufficient lead exposure.

There are few studies in animals showing lead to be a teratogen. In rats, lead had been shown to produce urorectocaudal malformations, while in hamsters, tail abnormalities have been reported. Cardiac abnormalities have been shown to occur in chick embryos. What is known about fetus effects in human? In the 19th and early 20th centuries, there were reports of macrocephaly of children whose parents lived in pottery making villages in Germany and Hungary. There are few other data to implicate lead as a human teratogen. (2,6)

Fahim et al (7) compared 253 pregnancy outcomes from women living in the Missouri lead belt to a similar number of controls living elsewhere in Missouri. The percentage of normal deliveries were 70 percent among the lead belt women and 96 percent among women from the control area. The percentage of premature infants born in the lead area was 13 percent compared to 3 percent in the control area. Finally, 17 percent of the pregnancies of lead belt women resulted in premature rupture of the amnionic membranes, compared to 1 percent in the control area. The infants from the lead belt area had a 3 or 4-fold increase in the cord blood lead levels compared to the controls. These data suggest an

adverse effect on the fetus. It is unclear if the effects are due to teratogenesis or direct fetal toxicity.

In 1984, Needleman et al. (6) reported on the evaluations of 4354 births in a Boston hospital for congenital malformations and maternal blood lead levels. Table 1 is adapted from the Needleman et al data. They divide the blood lead results into four categories with almost equal number of births. The categories are 0 to 4.8 μg/dl, 4.9 to 6.5 μg/dl, 6.6 to 8.6 μg/dl and 8.7 to 35.1 μg/dl. They found a statistically significant linear trend for total malformation with increasing blood lead levels. While there was no trend for only major malformations, there was a statistically significant trend for minor malformations. Interestingly, there is an inverse trend for infants born with respiratory distress and blood lead results. These data suggest lead is associated with minor malformations and may somehow reduce respiratory distress in newborns.

Needleman et al conducted a covariate analysis of relative risk for malformation at selected blood levels. They found an increasing relative risk with increasing maternal blood levels as shown in Table 2 using the blood lead level of 0.7 μg/dl as the baseline comparison level. Maternal blood lead levels of 24 μg/dl had a corresponding relative risk for malformation of 2.73. One should remember that the types of malformations Needleman et al found in excess were considered minor. Any routinely established malformation surveillance system would have detected few if any of these malformations.

The most widely quoted study of the effects of lead on male workers is the 1975 study by Lancranjan et al (8). They showed a dose response relationship for decrease in sperm count, decrease in sperm motility and increased in abnormal sperm morphology with increasing lead intoxication categories. On the other hand, they showed an inverse dose response relationship for libido, pathologic erections, pathologic ejaculations, and orgasms with

lead intoxication categories. They reported inconclusive results for the number of normal pregnancies per couple, frequency of miscarriages, incidence of ectopic pregnancies and premature births with lead intoxication categories. Based on these data one sees a diminution of semen quality accompanied by increase in sexual performance with increasing lead intoxication categories.

Wildt et al (9) studied the semen quality of 16 lead exposed men and compared them to 16 non-exposed controls. The mean blood lead level was 46.1 μg/dl for the exposed group and 21.1 μg/dl for the control group. There were no differences between the two groups for sperm count, over-all sperm morphology, prostatic function and vesicular function. The lead exposed group had better sperm motility and number of live spermatozoa at end of 1 hour than the non-exposed group.

Cullen et al (10) reported that, in six men with whole blood lead levels ranging from 66-139 μg/dl, two were azoospermic and two were oligospermic with poor sperm motility. Finally, in a yet unpublished study of approximately forty men with a mean blood lead level of 43 μg/dl, no effects were found on sperm count, sperm motility or sperm monphology.

Thus, the current data on lead effects on testicular function in humans are inconsistent. Some of these inconsistencies can be explained by differences in dose and/or methodology. Others cannot be explained at present.

There are numerous references which indicate that the fetal blood lead is either equal to or closely equal to the maternal blood lead in the second and third trimester of pregnancy. There was some discussion at the time of the OSHA lead standard that lead did not cross the placenta during the first trimester. Regardless of the validity of the first trimester lead exposure, clearly the fetus is exposed to lead levels similar to the maternal blood lead level during the majority of pregnancy. Manton (11) reported on a longitudinal study of blood lead levels in a

woman before, during and after pregnancy. He reported a doubling of pre-pregnancy blood lead levels during pregnancy and suggest mobilization of lead from bone during pregnancy as the mechanism. Since lead is an accumulative toxicant which is stored in the bone, with a half-life in the body of 5 to 7 years, a woman with a significant body lead burden would pose a potential hazard to any conceptus for many years after exposures. In addition to placental transport, lead can also be transmitted in human breast milk.

We do not know what is the hazardous lead level for the embryo and fetus. What is known is for children based on experiences of lead intoxication. At present, the Centers for Disease Control (CDC) considers a child with blood lead levels in excess of 25 μg/dl to be considered lead poisoned or intoxicated.

In the more advanced industrialized societies (ones in which there are generally acceptable controls for worker lead exposures), who is at the greatest risk from the potential toxic reproductive effects of lead. It is neither the adult male nor the adult female. Rather it is the embryo/fetus of the pregnant female worker and its developing central nervous system. The individual with the next highest risk would be the nursing infant of a woman lead worker. If all members of society are to be protected, then the standards would have to be protective of these two high risk groups. Neither is a group in which most workplace standards are directed.

What are the current guidelines or standards for blood lead levels for adult males and females working with the material? Table 3 as adapted from Zielhuis (12) shows acceptable worker blood lead levels for both males and females for a number of countries or institutional organizations. The World Health Organization (WHO), United Kingdom (UK) and the Federal Republic of Germany (FRG) have markedly lower levels for female employees compared to males. Contrary, the

European Economic Community (EEC) and the United States (USA) have the same level for both male and female employees. Based on the CDC definition of lead poisoning for children and assuming the fetus is at least as sensitive as young children, then all of the children born to women workers whose employers followed the respective guidelines or standards would be considered to be lead poisoned or intoxicated. It would appear that all of these organizations and countries have decided that it is satisfactory social policy to allow a subset of children have dangerous lead exposures in utero and to risk developing serious neurological deficits which most likely will be permanent. Other papers presented at this symposium, having reported central nervous system deficits in children at blood lead levels less than 20 μg/dl, only heightens the concern for these children. One must wonder about the ethical and moral justification for such policies.

The preceding discussion about the potential fetal effects have significant implications towards employment policies for men and women. Historically, in the United States, the policy of the lead industry has been to exclude women from work with lead or at least women of child bearing age. While this is the simplest policy to administer, it clearly is discriminatory if one considers demographics of family size, age and parity, marital status and the widespread use of birth control in the US. At present, the number one method of birth control is surgical sterilization; vasectomies are a significant portion of such procedures. In some of our studies, from 20 to 40 percent of the blue-collar male work force have had vasectomies. Any policy about employing men and women or restricting the employment needs to consider the above listed factors. Personally, based on the potential for serious fetal effects plus the prolonged half-life of lead in the body, I would not advise any woman who wants to have children to work in a job with lead exposures. The same would be true for a nursing mother.

Finally, if societies are going to allow fetal exposures of relatively high lead levels due to maternal work exposures, societies must be obligated to examine and follow these children over time to determine if any adverse health effects have or are occurring. One should also realize that no investigator could ethically conduct such a study of exposing women volunteers who would subsequently become pregnant to determine if the offspring were suffering from central nervous system effects of lead. But since society has deemed such exposures at work to be legal, society has the ethical obligation to determine if it has committed folly.

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TABLE 1

Pre-Natal Lead Exposure and Congenital Anomalies

	Lead Category			
Characteristic	1	2	3	4
Range of Blood Lead (ug/dl)	(0-4.8)	(4.9-6.5)	(6.6-8.6)	(8.7-35.1)
Malformations				
Any	7.7%	6.7%	9.1%	9.6%*
Major	2.9%	2.3%	2.9%	2.9%
Minor	4.8%	4.4%	6.2%	6.7%*
Respiratory Distress	6.4%	5.3%	5.1%	4.4%*
Total Number of Births per category	1118	1068	1105	1063

* Significant ($p<0.05$) linear trends

[Ref: Needleman et al, 1984]

TABLE 2

Covariate-Adjusted Relative Risk of Malformation at Selected Blood Lead Levels

Blood Lead [ug/dl]	Relative Risk
0.7	1.0
6.3	1.87
15.0	2.39
24.0	2.73

[Ref: Needleman et al, 1984]

TABLE 3

Acceptable Blood Lead Values [ug/dl]

Organization	Workers	
	Male	Female (reproductive age)
WHO [1980]	40	30
UK [1980s]	80	40
FRG [1984]	70	45
EEC [1982]	70	70
USA [1978]	50	50

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

AFFIDAVIT OF J. JULIAN CHISOLM, JR., M.D.

STATE OF MARYLAND)
) ss.
COUNTY OF BALTIMORE)

J. JULIAN CHISHOLM, JR., M.D., being first duly sworn, on oath, deposes and states as follows:

1. I am a pediatrician licensed to practice medicine in the State of Maryland. I received my undergraduate degree in 1944 from Princeton University and my medical degree in 1946 from Johns Hopkins University School of Medicine. Attached hereto and incorporated by reference as Exhibit A is my curriculum vitae which lists, among other things, my educational background, professional experience, professional society and committee memberships, and consultant positions.

2. I am the Senior Staff Pediatrician at Francis Scott Key Medical Center and a staff pediatrician at Johns Hopkins Hospital. My particular area of expertise is the study, treatment and prevention of lead poisoning in young children.

3. I have been the Director of the Lead Program at the John F. Kennedy Institute located in Baltimore, Maryland, since 1975. In my capacity as Director of the Lead Program at this Institute I operate a clinic for the prevention of lead poisoning in children. As

part of my work at the clinic I examine and treat children with lead poisoning on a weekly basis.

4. I am an Associate Professor of Pediatrics at Johns Hopkins School of Medicine.

5. Attached hereto and incorporated by reference as Exhibit B is a current bibliography which lists my various professional publications, the vast majority of which deal with the issue of the effect of lead exposure on children.

6. During pregnancy the lead in the mother's blood transfers across the placenta to the fetal circulation. The concentration of lead in the fetal tissue increases rapidly during the last trimester of pregnancy. At birth, the fetus generally has the same blood lead level as the mother. However, the fetus is medically judged to be at least as sensitive, and, indeed, is probably even more sensitive to lead than the young child. This is particularly true during the latter part of the gestation period when the central nervous system of the fetus is developing very rapidly and is extremely susceptible to the toxic effects of lead. Medical studies released in the last year or two out of Boston, Cincinnati and Port Pirie, South Australia suggest that exposure to the fetus of blood lead levels as low as 10 micrograms presents grave risk of permanent harm to the central nervous system of the fetus. The risk of harm to the fetus increases proportionately with the i of blood lead levels over 10 micrograms. Such harm includes stillbirth, reduced birth weight and gestational age, and retarded cognitive development which may result in learning deficiencies and behavioral disorders.

7. There is no medical evidence that lead exposure to the adult, male or female, has any adverse effect on the offspring. Rather, the available medical evidence establishes that it is the exposure directly to the fetus, through the pregnant woman, which causes harm to the offspring.

8. Because the fetus reacts adversely to lead at much lower levels than adults, it is my medical opinion that, in order to protect the health and safety of the fetus, under no circumstances should women capable of bearing children be permitted to work in any area where their blood lead levels may rise above 10 micrograms per deciliter. Conversely, in my medical opinion it is generally safe for males and nonfertile females to work in areas where blood lead levels may reach 50 micrograms, at least where there are no other indications of ill effects. It is the fetus' special susceptibility to lead and dependence on the maternal environment which medically requires the different treatment of fertile females.

9. In my opinion there is medical justification for including in this prohibition women who are capable of bearing children but who do not have any present intention of ever having children. This medical opinion is based on the fact that many pregnancies are unplanned and occur despite the use of even the most reliable methods of birth control.

10. In my medical opinion, excluding only women who are actually pregnant from work areas where there are elevated blood lead levels would not sufficiently protect the health and safety of the unborn child. My opinion is based on the substantial medical evidence which establishes that lead remains in the body for a significant period of time after removal from a high lead environment. Lead builds up not only in the blood and soft tissues, but is also stored in the bones. Following removal from the high lead environment, as the lead built up in the blood and soft tissues leaves the body, the lead in the bone begins to turn over, thus maintaining high blood lead levels even long after removal. As a general rule of thumb, it takes approximately two or three times as long for the blood leads to decrease as it did for such blood levels to increase. Therefore, if a woman is exposed to blood lead levels in excess of 25

or 30 micrograms for any length of time, such levels will not decrease sufficiently to avoid damage to the fetus, even if she is removed when the pregnancy is discovered. Moreover, because the bones may decalcify during pregnancy in order to provide the fetus with calcium, there may be an additional danger of transfer of stored lead to the fetus.

11. I have reviewed the Fetal Protection Policy which is currently being utilized at the Battery Division plants of Johnson Controls, Inc. In my medical opinion this policy is necessary and effective to protect the health of the unborn children of female workers from the serious risk of harm that is likely to result from exposure to blood lead levels of over 30 micrograms. At the time the Fetal Protection Policy was adopted in 1982, the general consensus of medical opinion was that the upper limit of acceptable lead exposure to young children, and by extension, the fetus, was 30 micrograms. However, it has always been my medical opinion that the fetus should not be exposed to blood lead levels above normal community levels. The recent Boston, Cincinnati and Port Pirie medical studies on infants confirm this opinion and suggest that the upper acceptable limit of fetal exposure should now be lowered to 10 micrograms.

13. This Affidavit is made and submitted in support of the Motion for Summary Judgment of Defendant Johnson Controls, Inc., in the above-entitled action.

Dated this —— day of August, 1986.

[Signatures Omitted in Printing]

* * * *

[EXCERPTS OF SILVERSTEIN DEPOSITION]

(Jones Aff., Ex. A)

* * * *

[6] Q Are you familiar with the fetal-protection policy which is the subject of this Court Action, and which is in effect at the Plants of Johnson Controls?

A I believe so.

* * * *

[7] Q (BY MR. JASPAN) Do you have any problems with that policy from a medical point of view or otherwise?

[8] A Yeah. I think it's—that it's based on incomplete and an incorrect understanding of medical science, and that it creates a, a set of conditions that are detrimental to public health.

Q Okay. Can you be more specific as to what parts of it you have problems with, and the basis for your disagreement?

A The, the policy's stated-objective—may I—the policy' stated-objective is to protect health of employees, an. to protect the health of unborn children. The method chosen to do that is to exclude women of childbearing capacity from certain jobs under certain conditions. I think that that—those actions are insufficient to either protect the health of battery-plant employees, or to protect the health of unborn children.

In fact, the implementation of that policy would leave conditions such, that the health of unborn children and the health of employees would be in great jeopardy.

Q Okay. In what way does that put the health of unborn children in great jeopardy?

A The policy is silent with regard to the dangers to the male-reproductive system, and to the development of children whose fathers have been exposed to lead.

[9] Q Any other way is it—any other way that it is detrimental to the protection of the health of the unborn children?

A Insofar as the risks to reproductive health from lead are shared equally by men and women at all exposure levels, the policy is, is ineffective.

Q And you also indicated that the policy fails to protect the employees?

A Yes.

Q In what regard?

A The policy erroneously states that the risk to the unborn child is present in a much lower blood level than adults, and insofar as it's designed to provide a greater level of protection, it leaves adult employees at risk.

* * * *

Q Okay. If I understand what you've said, and please correct me—let me try to put it in my lay language—the risk to an unborn child is created whether it's the mother or the father who is exposed at same levels?

A Correct.

[10] Q And the risk is similar whether it's the mother or the father who is exposed?

A Correct.

Q And secondly, the—according to what you've told us, the risk to the adult is similar to the risk to the child at the same levels, or to the unborn child?

A Correct.

* * * *

Q Let's talk about first—the first part of what you indicated, namely that the risk to the unborn child [11] is equal, whether it's the mother or the father who is exposed to a particular lead level.

A Uh-huh, uh-huh.

Q On what do you base your conclusion that the risk is similar with respect to whether it's the mother or the father who is exposed?

A Okay. There is an extensive body of scientific literature dating back into the mid 1800's, that—which has subsequently been reviewed by generations of medical experts. And that body of scientific literature indicates

without question that when either men or women are exposed to lead, that there are risks and damages that occur in the area of reproductive health.

There is a great deal of information that, that demonstrates that lead is toxic to the reproductive systems of adult men and women that damages the germ cells, the ovaries, the testes of women and men respectively, that this physical damage to the germ cells is then expressed as defects in reproductive, reproductive function including sterility, stillbirths, low-birth rate, alterations in, in reproductive functions such as impotence, in addition to the effects on the reproductive tissues of men and women themselves. It's been demonstrated in both [12] animal and human studies that offspring born to, to either the lead-exposed mother or father can sustain damage.

Q Resulting from—other than the exposure to the—exposure to the reproductive system, or damage to the reproductive system?

A No. Presumably that, that—we're talking about a constellation of effects on reproductive integrity, and there are undoubtedly a variety of mechanisms through which these effects are, are expressed, but they're all reproductive-health effects.

Q I take it, your conclusions in this regard are based upon your review of the literature?

A That's correct.

Q And not based upon any independent studies, or experiences, or examinations that you've conducted?

A That's correct.

Q Would you identify—well let me withdraw that. At what levels of lead exposure as expressed in blood of the adult, in the mother or the father, do these concerns arise, in terms of the actual damage to the germ cell, based upon your review of the literature?

A Well first of all, the, the levels that have been associated with, with effects have been reported down to and below 20 micrograms of lead in blood, whether [13] either males or females have been exposed. And secondly,

I think it should be made clear that the effects are of equivalent type and magnitude, whether males or females have been exposed at similar blood levels.

Q Then let's talk in terms of specific studies, or specific sources of your conclusion. Do you have specific articles or studies that you rely upon for that statement that the effect on the reproductive system of both the male and the female have been shown at levels below 20 micrograms?

A Yes. As I indicated, there is a substantial body of scientific literature dating back to the 1800's, and if you'd like, we can start to—start to go through it.

* * * *

[14] A The first article is entitled, Some Actions of Lead on the Sperm and on the Male Reproductive System. This article appeared in the American Journal of Industrial Medicine in 1983. It's authored by Thomas, Thomas & Brogan, T-h-o-m-a-s, T-h-o-m-a-s & B-r-o-g-a-n. This is a review article that contains approximately a hundred references, and indicates—gives information in there, areas of relevance. One is that it—that it demonstrates that it—that historically there have been a large number of studies done during periods of time when lead exposures were generally higher than they are today, showing that [15] there are reproductive effects to the, the systems of both men and women, and their offspring exposed to lead, including decreased fertility, miscarriages, stillbirths, damage to, to sperm, and probably various types of birth defects.

Secondly, the—this review article reports nine more-recent studies done on various animal species that indicate that male animals exposed to lead sustain severe reproductive damage, including abnormal sperm viability and performance, abnormal sperm shape, degeneration of the tissues of the, the testes, and infertility.

Thirdly, the study reports that—I'm sorry, this paper reports ten studies on occupational groups, in which male

workers and female workers exposed to lead has been found to sustain chromosome damages. It also indicates that, that half of those studies were done among battery-plant workers, and makes the point that the chromosome damage which is measured in generally white blood cells increases the, the plausibility that, that the damages to sperm that's been reported occurs through damage to the genetic material of sperm, and that the damage to sperm being genotoxic damage can then be expected to express itself as develop—developmental [16] abnormalities in the offspring that, that are, are successfully conceived, and successfully survived a term.

Q Does that article indicate the level at which the damage to the reproductive—the lead level at which the damage occurs, which affects the offspring? What level of the exposure of the adult?

A This particular articles does not go into, into detailed critiques of the—of the various studies that it reports on. However, what I would like to do is move on to some of those studies, and we can talk about them directly, rather than relying on—

Q Fine.

A —Thomas & Brogan's view.

* * * *

Q Okay. Next?

A In 1972 Hilderbrand, H-i-l-d-e-r-b-r-a-n-d, published [17] an article entitled The Effect of Lead Acetate on Reproduction. And this was in the American Journal of Obstetrics & Gynecology. This was a study in which rats were fed an organic lead in the—in the female rats, at blood-lead levels between 14 and 30 micrograms. There were irregularities of the reproductive cycle, and at blood-lead levels, which reached 50 micrograms per hundred millimeters of blood, there were ovarian cysts, and a decrease in the maturation of eggs.

In the male rats who were exposed to lead, there was impotence, and a decrease in sperm motility, sperm moyement at blood-lead levels between 14 and 26 micrograms.

When the blood-lead levels reached 50 micrograms, there was a decrease in the maturation of sperm, and there was testicular damage that was found. Those are the basic findings in the Hilderbrand study.

Q Are there—is there evidence that the levels, blood-lead levels by which a—of a, an animal, and similar to the blood-lead levels of a human will be affected in the same fashion?

A One of the important reasons that so many studies have been done on the mammalian species of this type is that the, the biologic and physiologic properties [18] of, of the rodents are substantially similar to the—this—the equivalent systems in humans, and so that the results do have meaning for human experience.

Q And I assume that by that, there would be reason to believe that the nature of the damage caused to the rats could or would be similar to the damage caused by the adult systems?

A There is not only reason to believe that, but evidence to show that.

Q Now my question goes to the levels at which that lead—and could you show me, is there evidence and could you cite for us evidence if you believe there is, showing not just that the nature of the damage to the adult and to the human is similar to that in the rat, but whether the levels, the blood-lead levels at which that type of damage is caused in the rats is substantially similar to the levels at which similar damage is caused in the adult?

A Yes. I, I, think that that information exists, and that as we continue this discussion, that we will make our way through those arguments and that evidence.

Q Can you cite a particular article offhand, before we even get to it?

A There is a, a, a study that was done by NIOSH, [19] entitled Reproductive Outcomes in Wives of Lead-Exposed Workers. This shows some similar effects at similar blood levels in men who are exposed in battery plants. I am afraid that evidence in human studies of the

kind you're asking for doesn't exist with respect to the effects on the female-reproductive system, that the conclusions that have been drawn by scientists over the years regarding the dangers to the female-reproductive system are of two indirect sorts. One is extrapolation from animal studies, and the, the second is from studies of lead-exposed children.

Q Let me go back to the findings in the Hilderbrand study. As to the male rats, you indicated that blood leads between 14 and 26 had resulted, according to that study, in impotence and decrease in sperm motility; isn't that correct?

A That's correct.

Q In terms of the effect on the child?

A Uh-huh.

Q Is there evidence that impotence has an effect on an unborn child? Would impotence be total inability to conceive, or—

A Presume—presumably.

Q So I assume by definition then, when there is [20] impotence, there is no effect on the—

A There would be functional infertility.

Q And the effect of decreased sperm, decreased sperm motility, how would that affect an unborn child?

A Well if we were considering the Hilderbrand study alone, we would have to speculate about that, and the reasonable speculation would be that the effect might be twofold. One is that abnormal sperm might be less likely to fertilize an egg, and would result in decreased fertility. Secondly, secondly, we could—we could postulate that abnormal sperm, insofar as they carry damaged genetic material, might, if an egg was successfully fertilized result in damaged offspring, and we would have to guess as to how that damage might be expressed.

Q And that would simply be speculative at this stage, of the latter point?

A If the only study in the literature were the Hilderbrand study.

Q Proceed.

A Let me refer to a paper published by Wyrobek & Bruce, which is a chapter in a book called Chemical Mutagens, and it's titled, The Induction of Sperm Shape Abnormalities in Mice and Humans. These scientists report on a large series of studies that they have [21] done in which animals have been exposed to a variety of chemicals, and the shape of sperm has been studied. And with respect to lead, they report two types of effects in mice. The first is that they find that when mice are exposed to lead, inorganic lead, that with increasing exposures to lead there are increasing proportions of abnormal sperm. And they provide specific evidence to that effect in this study. Secondly, they report on a different type of investigation, one in which mice were exposed to lead, and then the offspring of those mice, the next generation is studied, and they find that in the offspring of mice who have been exposed to lead, that there is an abnormally-high proportion of individuals with abnormal numbers of abnormal sperm.

They conclude from these studies that sperm abnormalities are caused by lead exposure, and that those effects appear to be heritable effects, and that sperm shape therefore is a function of genetic information, abnormal sperm shape, indicating genetic damage, which can be expressed in later generations.

Q Does that study indicate the level of lead exposure in the parent at which the abnormality is likely to occur?

A The studies that Wyrobek & Bruce did, did not report [22] blood-lead levels. They report exposure levels. And while it's fairly easy to draw a, a relation between blood-lead levels in a mouse, and blood-lead levels in a human, it's much more difficult to draw a relationship between a dose of lead in the diet of a mouse, and the blood-lead level in a human being. And they don't provide that kind of information. What they do show is that there are consistent dose-response relationships between sperm abnormalities and lead exposure.

Q What do you mean?

A So that higher doses are associated with greater abnormalities, and lower doses, while still producing abnormalities, are associated with a lesser number of abnormalities. And their information does not indicate nor suggest that there are thresholds below which exposure would not produce sperm abnormalities.

Q Does that study provide an indication of the nature of the abnormalities of the sperm, and the effect of those abnormalities on the offspring, other than what you've testified as producing abnormalities in the sperm of the offspring?

A In—they are—they are studying sperm shape, as an indicator of genetic damage, and the ultimate effects of that damage, based only upon their studies [23] would be speculation.

* * * *

The next study is entitled, The Reproductive Ability and Progeny of, of One, Lead-Toxic Rats. This was authored by Stoe, S-t-o-e, and Goyer, G-o-y-e-r, and published in the Journal, Fertility and Sterility, in 1971.

Stoe and Goyer fed rats inorganic lead with their diets, and they then mated rats, and observed the outcomes of subsequent pregnancies, and they looked at four different groups. They looked at the outcomes of pregnancies that had occurred from the mating of two unexposed rats. They looked at the [24] outcomes of pregnancies from the matings of rats that had both been exposed to lead, and they looked at the outcomes of pregnancies when either the male or the female, but not the other, were exposed. And they found that when either the male or the female were exposed to lead, there was decreased size of litters, that there was decreased birth weight of offspring, and decreased survival of offspring shortly after birth.

Q Any further conclusions from that study?

A They concluded that the data identifies specific deleterious paternal and maternal effects of lead toxicity

upon rat reproduction, and that the toxic effects were at least in part a function of genetic damage.

Q Do they draw any conclusions with respect to human exposure through lead?

A No.

Q From that study are you able to conclude the levels at which human exposure might create similar types of damage or effects?

A They—from this study alone, no. They didn't measure blood leads. However, we know from the Hilderbrand study, for example, that damage to the reproductive systems of the adults occurs at levels [25] down to 14 micrograms. And I think it would be a reasonable conclusion that the effects on the offspring measured by Stoe and Goyer are a result of that same type of damage to the adult-reproductive systems.

Q The Hilderbrand study was again the adult-reproductive system of animals of some type?

A Correct.

Q Rats, I believe on that basis?

A Correct.

Q Any further studies on which you relied for your conclusion?

A Let me refer you to a study entitled The Influence of Parental Lead Exposure on Subsequent Learning Ability of Offspring. This was published in the Journal called Pharmacology, Biochemistry and Behavior in 1975. And the lead author is Brady, B-r-a-d-y. Brady again looked at a group of rats who were exposed to lead, and in particular looked at the offspring to rats who had been exposed, and once again looked at the offspring in different groups, depending on whether the, the mother or the father, both or neither had been lead-exposed and in this case the study did not look at any of the, the specific measurable anatomic effects that for [26] example Stoe and Goyer looked at, but rather focused on development of the young offspring, and specifically Brady looked at learning ability on a discrimination test. This

was a test in which the, the infant animals had to perform a, a task that required discriminating between different visual stimuli and various measurements were taken that indicated how successfully these infant animals were able to learn. And Brady found that animals born to parents, both of whom had been exposed to lead, had a markedly-decreased learning ability, and that animals born to parents, one of whom was exposed to lead, whether that was the male or the female also had a substantially-decreased ability to learn and to perform.

Q Did that study identify in any way the levels of lead exposure correlating to this decrease in learning ability?

A This study didn't measure blood leads, and did not attempt to guess what those blood-lead levels might have been.

The authors do indicate they believe the effects that were measured are a result of damage sustained to the reproductive systems of either the male or the female. And insofar as that's true, we have to look at other evidence, such as we've already [27] discussed, that indicates the type of damage that's—that occurs to the reproductive system of lead-exposed animals. And we know from the other studies that that damage occurs at extremely low levels of exposure of blood lead, as measured by blood-lead levels.

Q You're referring back to the Hilderbrand study again?

A Right.

Q Any further articles on which you relied for the conclusions that you expressed earlier at this point?

A Huh-uh. There is an article that was published in the Journal called Infertility, in 1978, by Braunstein, B-r-a-u-n-s-t-e-i-n, entitled Hypogonadism, H-y-p-o-g-o-n-a-d-i-s-m—in chronically lead-poisoned men—and this was a—this paper reports a series of patients that these investigators examined and treated. There were 10 men with occupational lead exposure, and they report that

these men had noted a decrease in sexual drive following exposure, and that on two of the men, testicular biopsies were conducted which demonstrated scarring of the testicles, decrease in sperm count, and other cellular abnormalities. Four of the seven—four of the 10 men that they studied were identified as, as being lead-exposed, but without [28] clinical evidence of lead poisoning, despite a range of exposure from 1 to 23 years, and that the others had exposure presumably in higher concentrations, so that they had been judged in higher clinical-lead poisoning with other symptoms.

Q Do they indicate the lead exposure of the 10 individuals?

A What do you mean by lead exposure?

Q Blood levels?

A No, they don't indicate blood levels.

Q Would it be fair to conclude that this study would not allow one to draw conclusions as to the blood-lead levels at which the effects described would occur?

A Wait, excuse me, blood lead—they, they do report on blood-lead levels, and they indicate that at the time of testing the average blood lead among the lead-poisoned group was 38, and among the lead-exposed group it was 29. And they also indicate that for both groups that at some time in the past there were higher blood leads that were measured up to 80 and above.

* * * *

[32] Q Let me rephrase it, so we have it clear on the record. It's that—your earlier testimony that certain findings or conclusions were reached in that Braunstein study, including decreased-sex drive, scarring of the testicles and decreased sperm count?

A Uh-huh.

Q My question specifically is, the findings and conclusions of that study could have resulted from recent lead exposure, or lead exposure sometime earlier, which I understand reached and exceeded 80 micrograms?

A Yeah, that's correct. And from this study we can't tell what the, the responsible lead levels might have

been. I want—I want to indicate that in fact there was some effort made in, in this study to [33] look at motility and shape of sperm, and they did not report any abnormalities of those sorts.

Q And if I understood your earlier testimony, motility and shape of sperm would reflect recent exposure, as opposed to the more-historic exposure?

A Well for, for those kinds of abnormalities, it would be easier to reach a conclusion about the time of exposure. With some of the other abnormalities, it's simply impossible to determine that.

Q And the absence of decreased motility or abnormal shape of sperm would indicate that the recent exposures did not cause at least that type of damage?

A At least that, yeah. It indicates that they didn't cause damage, that they didn't find—or it indicates that that damage wasn't caused in such a way that using their methods, they were able to find it. That's all that it indicates.

* * * *

A There was a study that was authored by Cullen, C-u-l-l-e-n, published in the archives of Environmental Health in 1984, entitled, Endocrine and Reproductive Dysfunction in Men Associated with Occupational Inorganic Lead Intoxication. And this report is on a series of tests done among seven men, who had [34] occupational-lead exposure, and clinical-lead intoxication with blood leads between 39 and a hundred, but largely above 60. And they found in this group that there were defects in the development of sperm, including abnormal-sperm shape and motility.

Q Anything further?

A Regarding that study, no.

Q Any further studies?

A Oh yeah. There is a study in the archives of Environmental Health, published in 1975 by Lancranjan, entitled The Reproductive Ability of Workmen Occupationally Exposed to Lead. In this study a hundred and

fifty men employed in a lead acid battery plant were investigated, and these men were divided into several different groups. There was a group designated as those with lead poisoning, whose blood leads were 74. There was a group with moderate, moderately-increased lead absorption, whose blood leads were 52, a third group with slightly-increased absorption, whose blood leads were 41, and a fourth group who were said to have physiologic-absorption of lead, whose blood leads were 23 micrograms. And the investigators looked at the motility of sperm, the movement of a sperm, the amount of sperm, and the shape of sperm, and they found that with [35] respect to all these measures of reproductive integrity that there was a relationship between lead exposure and effect, and that the effect was greatest among those with the highest blood leads, and that it was present though in lesser degrees among those with the lower blood leads, down to and including the group whose blood leads were 40, 41.

Q All three effects?

A This was true for all three effects. There is a, a table in their paper—excuse me, there is a figure in their paper which illustrates graphically the relationship between abnormally-shaped sperm and blood lead, and it demonstrates a very strong and consistent dose-response relationship, in which all of the lead-exposed groups who had blood leads that were higher than a completely nonexposed group had higher proportions of abnormal sperm, and this effect was noted, starting in the group of blood leads in the range of 40, and was progressively worse at the higher blood-lead levels.

Now they also looked at motility and amount of sperm, and they found the same relationship. In fact, for those measures, the relationship was even stronger and more marked.

Q Are you aware of any criticism of the men—the [36] Lancranjan study—are you aware of any criticism as to the manner in which that study was conducted?

A I'm aware that during the hearings that preceded the adoption of OSHA's current lead standards, that this study was discussed at great length by numerous witnesses before the OSHA panel, and that some of those who testified were critical of the study, but that when the body of evidence, which was a substantial body of evidence, and testimony was reviewed by the OSHA experts who were charged with the responsibility for establishing the lead standard, they felt that the language and study had scientific merit, and that conclusions could be reliably drawn about the reproduction damage to men exposed by lead, and that in particular the conclusions that Lancranjan drew were appropriate. The OSHA panel felt substantially strong about the study, so that they published in the preamble and attachment documents to the OSHA standard a fairly lengthy discussion of the language in paper, and their reasons for believing that it was a valid scientific study.

And I should also point out that the archives of Environmental Health in which this study appeared is a well-respected peer-reviewed Journal, so that in order to be published it was necessary that the [37] paper undergo critical review by experts in the field.

Q Anything further as to that study, or any further studies?

A No more with respect to that study.

* * * *

Q (BY MR. JASPAN) You are going to go into another article, I believe?

A Yeah. This is a research paper that was prepared by a group of NIOSH investigators, the lead investigator being Selevan, S-e-l-e-v-a-n. This is entitled, Reproductive Outcomes in Wives of Lead-Exposed Workers. This is dated December, 1984, and it is a NIOSH document that's available through the Federal Government's National Technical Informational Services.

Selevan looked at the reproductive outcomes in the families of 376 male lead battery-plant workers, and they obtained a—pregnancy information through interviews of the workers' wives, and they obtained information about blood leads through company records. Only the men in this study were exposed to lead, and lead exposures were classified into four groups, the unexposed group either had blood-lead [38] levels that were less than 25 micrograms, for a hundred liters of blood, or in some cases workers were considered to be unexposed during the period of time prior to employment, in an industry where lead was used. The second group were those that had blood leads ranging between 25 and 45 micrograms of lead, and they were the low-exposure group. The medium-exposure group had blood leads ranging betwen 45 and 60, and the high-exposure group had blood leads in excess of 60 micrograms. And the investigators looked at fertility, and they looked at fetal loss, in other words, early, early miscarriage, spontaneous abcrtions, stillbirths.

With respect to fertility, the investigators calculated what are called standardized-fertility ratios, in which the reproductive history among the families of the workers were compared with the reproductive histories for the Nation as a whole, with consideration being given to any differences there might be between the workers and the general population, in such factors as age, number of prior children, or pregnancies. And the results indicated that there were significant deficits in fertility, significant loss of fertility in the lead-exposed groups, and that those changes were found in all three exposure [39] levels. And those effects were noted when all the appropriate controls were made in the calculations for other factors that might plausibly explain the outcomes.

And in the group of workers who were between 25 and 45 micrograms, the fertility in their families was 73% that of the normal population. In other words, there was a 25% loss of fertility attributable to lead exposure

when only the fathers had been exposed to lead in a battery plant.

Now NIOSH did a second type of study in which they looked at a second type of calculation, in which they looked at fetal loss, and again they found that lead was associated with fetal loss.

Specifically the odds of, of having an adverse-pregnancy outcome were 30% higher among those with low blood levels, low blood-lead levels, and no cigarette smoking, low blood-lead levels among the fathers, and no cigarette smoking among the mothers. When compared with the nonexposed the nonlead-exposed controls, the adverse effects got worse, when in addition to lead exposure cigarette smoking was taken into account, so that cigarette smoking plus lead exposure was worse, in terms of reproductive outcome, than lead level alone.

[40] With respect to the fertility—excuse me, with respect to these fetal-loss findings, among those who—in any of the smoke—cigarette-smoking groups, there was an excess-odds of, of reproductive damage among all of the lead-level groups, but a consistent dose-response relationship wasn't found. In other words, the higher the workers with the higher blood leads, did not necessarily have greater effects than those with the lower-lead levels. This is consistent with the other pieces of the study, the infertility piece of the study. In, in fact, what's happening is that as blood-lead levels increase, not only is—excuse me—as blood-lead levels increase, the nature of the outcome, as well as the magnitude changes, so that at the higher levels of blood lead, the likelihood of infertility is increased, because the embryo or the fetus doesn't—is not even conceived, whereas at the lower levels of lead exposure damage is sustained, but the pregnancy is not necessarily terminated, and there are excesses in—excuse me, the pregnancy continues, but may be terminated during pregnancy, and the effects would be expressed, expressed then as early-fetal loss.

Q Anything further on that study?

[41] A No.

Q Did that study measure the blood leads of the mothers, and the possibility of exposure of the mothers through the fathers?

A Yes, it did. I'm glad you raised that. I had forgotten to point that out. The blood leads in the mothers were—the main blood-lead levels in all of the groups for the mothers were less than 16, and in the—in the families whose father's blood lead was less than 40, the mother's blood lead was less than 14.

Q Anything further in that study?

A No.

Q Any other studies or articles on which you relied?

A Well I don't want to go into, into detail on additional specific studies, but I do want to point out that the literature on, on these subjects, subjects, is truly voluminous, and that there are several authors who have reviewed and critiqued a much-wider range of studies than we've talked about so far. As far back as 1934 the standard textbook on Industrial Toxicology written by Alex Hamilton indicated that there is incontrovertible evidence both from animal experiences and from observations on human beings that lead has an injurious effect on [42] the cells of both sexes. And in subsequent editions of that textbook, those conclusions were strengthened in light of subsequent publications in the literature, so that in 1949 the textbook which at that time was authored by Hamilton and Hardy indicated that apparently lead poisoning in the fathers does not lead so much to interruption of pregnancy as to injury to the health of the child, and ten—the tendency to its early mortality.

And in the 1974 edition, the textbook again, as in previous editions, reported on a whole series of scientific papers, and concluded from these data—it is reasonable to conclude that lead is a poison to the germ cell, male as well as female.

There is a more recent edition. I think it's the 1973 edition of the same textbook, which continues to be the

standard textbook in the field, which reaches the same conclusions.

Now in addition to that, I want to point out that all of the articles that, that we've discussed have extensive bibliographies, and they all have articles that are testing hypothesis that have been generated as a result of other studies. So there is in effect a multiplier effect, and we've just skimmed the surface of the information in this area.

[43] During the hearings on the lead standard several years ago, a lot of this information, at least that which was current up until 1978 was discussed in public, and OSHA has summarized a lot of that information in the preamble, and the attachment to the lead standard. And so there are additional studies that are available by going through that OSHA material.

Q Are there any studies, other than the ones which you have discussed, which you specifically relied upon in terms of your conclusions, and more specifically that reflect levels at which male exposure—of blood-lead levels at which male exposure creates the damage that you've—the potential damage that you've identified?

A I've indicated the, the studies which have the, the most specific and immediate relevance to the kinds of judgments that we're trying to make, but it would really—really be a mistake to, to indicate that it's a, a—appropriate to draw a judgment on the basis of a single study, rather than a, a systematic and coherent review of a whole body of scientific information. Patterns of consistency and repeatability are as important as particular individual findings, and so I think that, that the judgments [44] that are reached really take into account a wide spectrum of information, but I have tried, to the best of my ability, to indicate some of the, the key findings.

It would be incorrect, because I went through in detail five or six studies, to tell you that there were no others, the details of which have relevance and importance.

Q The question is, specifically, are there other studies which you rely upon, which include findings as to specific levels at which male exposure creates hazards to the reproductive system?

A I think that's—that there probably are additional studies in this enormous collection of material, but none that, that I'm prepared to discuss in detail right now.

* * * *

Q (BY MR. JASPAN) Are you aware of other studies which [45] specifically address the danger of lead exposure to the unborn fetus?

A No, not when you—not when you phrase it like that. I'm a—unaware of, of human studies in which fetal health has been directly examined among lead-exposed populations. Now, if you are thinking of other types of studies, maybe you could clarify the question.

Q Are there other types of studies, other than human studies where conclusions have been drawn as to the dangers of lead exposure to the unborn fetus?

A There is a whole field of animal-developmental toxicology in which animals are exposed to a variety of chemicals, and adverse-fetal outcomes are studied, and those include studies on lead.

Q And do you have any opinion as to the danger to an unborn fetus of lead exposure?

A Yeah. Lead is a—lead is a very potent reproductive-toxin that affects the, the reproductive system of adult men and women, and to the—to their unborn children, during pregnancy and subsequently, and the effects are equally likely to be expressed, whether the exposure is to the male or the female parent.

* * * *

[48] Q And do you concur with those conclusions that have been expressed as to that concern, comparable—com—or similar to the—what the dangers of—to young children are, as relates to cross-placental exposure of lead of the fetus?

* * * *

A I think lead is a—is a danger, whether the adult man is exposed, the adult woman is exposed, children in their developmental stages are exposed, a fetus, or embryo in development are exposed, or the, the fertilizd egg in its earliest stages, as a unique organism is exposed.

And my conclusion is that the dangers are of equivalent type and magnitude, whether the exposure is through the female or the male side of the human race.

Q Is—isn't there also danger to the adult who is not capable—of the adult female who is not capable of bearing children, the adult male who is not capable of bearing a child? Are there dangers of exposure?

A Definitely. Lead is a poison that has many, many [49] effects beyond those to the reproductive system.

Q And would you agree that the level at which lead is a danger to the adult-reproductive system is comparable to levels at which lead is also a danger to other adult systems?

A Would you rephrase that?

Q Yes. It's my understanding that you agree with the conclusion that lead is a danger to the adult—to adult systems, other than the reproductive system?

A That's correct.

Q Would you agree that the levels at which lead is a danger to those systems, other than the reproductive system, are similar at least with respect to some of the other systems, as to the level at which lead is a danger to the reproductive system?

A That's correct, insofar as my belief is that lead has toxic effects at levels—at blood-lead levels, all the way from a hundred and greater, down through and below levels of 20 micrograms. I think there are reproductive hazards that are associated with exposures throughout that spectrum of exposures, and there are dangers to other organ systems of both adults and children at levels throughout that whole range of exposures.

Q Would you also agree that the extent of danger at [50] various blood-lead levels is greater in the child than in the adult?

A No.

Q You would conclude that the dangers to the adult systems occur to the same degree—well—and to the same degree in a similar fashion to the adult as to the child?

A I, I believe that there are substantial dangers to the adult and the child, that—at all the levels of exposure that I've just discussed.

Q Are you familar with the January, 1985 version of the statement by the Center for Disease Control—the Centers for Disease Control, entitled, Preventing Lead Poisoning in Young Children?

A Yes.

Q And you're aware of their change in definition modifying the definition of elevated blood-lead level in children from 30 micrograms down to 25 micrograms?

* * * *

[51] A All right. Okay. All right. I'm aware of this.

Q (BY MR. JASPAN) And in fact that was one of the basic modifications in the change to the 1985 version that you already talked about?

A I think that's a fair statement.

Q Is it your same conclusion that the same definitions and same levels of concern expressed in that article equally apply to adults?

A Most definitely, they should. If you look historically at the clinical and public-health practice with respect to lead exposures and toxicity, you'll find that the understanding about the toxicity of lead has improved over the years, so that the definitions of undue-lead absorption and lead toxicity have been restated numerous times, that each cycle, each regulatory cycle, or each cycle of public review or agency review over the last 20 years has resulted in a decreased—in a decreased level of lead exposure, which is deemed to be appropriate, and this is true for both adults and children then, and it's true for community

exposure, and occupational exposure, and it's also true that historically the assessments with regard to children have kept one step ahead of the assessments with respect to adults, so that if you go back ten years, 15 years, [52] 20 years, you'll find that the judgments that are—what are acceptable for children are higher than what they are, and the judgments as to whether they're acceptable to adults are a little bit higher than what they're stated to be for children, and higher than what they are today, but that invariably the, the statements and the policies from the scientific community and the regulatory agencies regarding adult exposures and toxicity have eventually caught up to the approaches used with respect to the evaluation of toxicity in children, and I would anticipate that this will happen again, because the scientific information that exists certainly is adequate to indicate that adults exposed to blood-lead levels below 40—below 30, down to 25 are affected in manners that are substantially similar to the types of effects that—for which there is concern in children.

* * * *

[53] Q * * * You agree that at particular points in time, including currently, the levels identified by Government agencies, by much of the literature, have, for the levels at which lead exposure is identified as dangerous for children, have generally been lower than those which have been identified for the adult?

A The levels identified by Government agencies and clinical—and the clinical literature usually identified lower levels of concern for children than adults. The levels identified in the broader scientific literature in fact indicate that the levels are comparable, and when, and for reason that, that all of us could speculate about, the public concern and regulatory policies are usually focused more strongly on the evidence on the children's side, than the adult's side.

Q And your conclusion would be that the levels are substantially similar for both groups?

A That there are—that there are significant and important effects at substantially similar levels for adults and children.

[54] Q Would the same be true for the unborn fetus?

A The same would be true for the unborn fetus.

* * * *

Q Can you identify for us any literature which draws the same conclusions that you have drawn with respect to the level of danger of lead exposure for the adults and children being equal, other than with respect to the effects to the reproductive system? In other words, if I'm understanding your testimony, it's your opinion that the dangers existed—similar, similar dangers existed at similar levels, even without regard to the reproductive system?

A Yes.

Q And I'm asking if there is any literature or studies that you are aware of that reflect that opinion, which if I understood your testimony is contrary to the clinical and Governmental publications?

A Well as I indicated before, there is a large volume of literature with respect to reproductive hazards of lead. You can multiply that—however tall that stack of papers would be, you can multiply that several-fold with regard to the literature concerning [55] other effects, and what I—I think it's a responsive answer to your question to indicate that my judgment is based on evaluation of a substantial body of scientific literature, that there is evidence on which I may base my judgments, but not—I'm not prepared—the specific question you asked was directed at the conclusions of others, and I'm not prepared to testify about the conclusions of others. My views are based on evidence that's been presented and developed by others, and there is a large body of that.

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[EXCERPTS OF SILBERGELD DEPOSITION]

(Jones Aff., Ex. B)

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[12] Q Basically what are the hazards of lead exposure?

A Under lead exposure as associated with a number of toxic effects on many organ systems, most prominently the brain, reproductive system, kidney, liver, neuroendocrine, blood forming organs, and possibly also as a carcinogen.

Q What is the impact on each of those organs?

A The impact in all respects is adverse. On the [13] brain lead can damage and even kill brain nerve cells leading to detriments in learning, memory, intelligence as well as changes in mood, and effects in the kidney, they damage the ability of the kidney to regulate body metabolism and excrete amino acids and other substances.

In the liver it can cause a condition known as porphyria or a derangement in heme synthesis which affects the ability of the liver to clear both endogenous and exogenous substances such as hormones and drugs. In blood forming organs lead inhibits the stability and formation of the red cell as well as the heme biosynthetic pathway which exists in the cells as well.

It also affects the calcium metabolism in the bone and elsewhere by affecting the regulation of vitamin D and other hormones which control calcium metabolism. Lead affects the reproductive organs, both the male and female, damaging cells in those organs and inhibiting their function causing infertility in both males and females. Spontaneous abortion in females as well as fetal toxicity very similar to toxicity in adult humans.

[14] As a carcinogen recent studies conducted by an industry consortium have found increased rates of certain cancers. There is nothing to suggest a specific type of cancer associated with excessive lead exposure, but there is an increase in mortality due to a number of cancers.

Q What studies are those?

A These are the studies by Clark Cooper undertaken on behalf of ILZRO, the International Lead, Zinc Research Organization.

Q In terms of these various organs that are affected by lead exposure, at what blood lead levels would adverse effects have been shown to appear?

A That's very difficult to say because in my opinion, scientific opinion, our current understanding of the mechanism of lead at the cel'uiar level would suggest that many of these effects, there is no clear threshold, and, in fact, what we discern as a level at which an adverse effect may be associated relates very much to the decision of our ability to measure it.

For instance, looking at the neurotoxic effects of lead which is an area of considerable study [15] over the past three decades, it's quite clear that our understanding of where adverse effects, that is, measurable detriments in brain function occur has been moving downward very very rapidly from levels in the area of 60 to 80 μg/dl blood lead which were considered to be associated with emcephalopathy and neurologic disfunction. Those were the levels that were talked about in the 1960's. In 1970's people began to consider the levels at 50 and 60 would also affect the brain and the peripheral nervous system. It's now, on the basis of studies by Baker and Hanninen, fairly clearly changes in mood can be seen in workers with blood levels in the range of 30 and 40.

As I said, when one explores the mechanisms of the effects of lead on the brain which has been in the area of my research, it is not clear that there is any threshold for these effects. Lead is a totally exogenous element. That is, it has no known function in the normal physiology of mammals including humans, and, therefore, any presence may have the potential to derange their function, particularly of essential elements such as calcium, sodium magnesium in the brain.

[16] Q What about in terms of the other organs that are effected?

A In terms of heme synthesis, again, based on our ability to measure it, again, the effective threshold based studies by Piomelli and others would be somewhere in the area of 7 to 10 μg/dl. This would relate both to the effects on the liver and the blood forming organs.

With respect to effects on the reproductive system, again, because of lead's effect on the liver, a derangement in neuroendocrine metabolism, since the liver is the main organ which metabolizes sex steroids, those may occur again at the same levels at which heme synthesis is deranged in the level of 7 to 10 μg/dl.

In adult males effects have been observed in levels as low as 25 to 35, with a relative lack of precision of dosage, and in females, levels, perhaps, of the same order, 25 to 40 one might expect to see effects.

In terms of increased spontaneous abortion, those studies which have been done in animals suggest that it takes a relatively high dose to cause failure of [17] implantation in spontaneous abortion. In terms of fetal toxicity, that is, the sensitivity of the embryo or fetus to lead, there is no evidence as yet, in my opinion, to suggest that the fetus is more sensitive than the postnatal child, so that levels of sensitivity for the fetus in terms of the neurologic development or organ development is probably similar to that of a child in the range of 10 to 25 μg/dl.

Q Let's go back. You talked about Heme Synthesis in terms of 7 to 10 micrograms.

A Right, but I want to state again very clearly in my opinion there are no clear thresholds for any of these effects of lead. These are the levels at which adverse effects have been noted with statistical significance in clinical studies. However, there is no reason to assume that below these levels for any particular organ system there would be no effect.

Q What is the general level of the population in Washington, D. C.? What is your estimate?

A In Washington, D. C., based on the Hanes II survey I would estimate that the median blood levels of this population are probably around 14 μg/dl. The [18] median for the U.S. as a whole is between 10 and 12, depending upon age, sex, race.

* * * *

[21] Q You made a statement that in your opinion the fetus at least at this point is not evidence that it is any more sensitive in the young child.

A That's correct.

Q Is the young child any more sensitive than the adult?

A The young child in terms of the nervous system impairment may be more sensitive than the adult.

Q Why is that?

A There are probably two reasons for stating that. One is unconnected with lead. Our knowledge of the prenatal and postnatal development of the brain suggest that the human brain, since it is still forming during the last trimester and in the first six years of postnatal life, is quite sensitive to the influence of aminobiotics of all sorts including lead. Moreover, since the brain is not capable of cellular repair, any damage, [22] in fact, being irreversible or difficult to compensate for.

In addition, more specifically related to lead, thee is evidence that the young child absorbs more lead per given dose and, in fact, more of that lead may reach the brain that in the adult. However, when I say that recent information on the effects of lead on the heart in man, adult men, may cause one to revise this opinion that the young child is more sensitive because increases in blood pressure and risk of hypersensitive heart disease have not been described in men with blood lead levels in the range of 10 to 20 μg/dl.

Q What studies are those?

A There is a series of studies published by Pirkle and Colleagues, 1985.

Q In terms of the young child, at what blood lead levels is there an indication that there is an adverse effect on the nervous system?

A Certainly in my opinion blood lead levels between 10 and 20 μg/dl.

Q On which studies do you rely for that?

A Primarily studies by Needlemam and Colleagues as [23] well as Lansdown, Winneke, Odenbro, Otto and a large number of other studies in this area.

Q Any of those relate to the fetus rather than the young child?

A One of the most recent studies by Needleman relates to the fetus as well as the young child. It's impossible to exclude the two, separate the two.

Q What was the Needleman's conclusion in that study?

A This was a recent study looking at children from time of birth and grouping them in terms of cord blood, that is the amount of blood in the fetal circulation measured at term of birth, and he did report decreased learning ability, behavioral changes as measured by appropriate tests for infants which had been observed in these infants now from, I think, three months now through 18 months. The most recent being by Ballinger and Needleman which are correlated with blood lead levels.

Q What is the blood brain barrier?

A Blood brain barrier is physically probably the capillary endophelial cells which surround the small [24] capillaries of the brain forming very close junctions, cell/cell connections which obstruct or prohibit the entry of relatively large molecules into the brain.

Q Would it protect the brain from lead absorption?

A It does not appear to in that proteins which transport calcium which resembles lead in being a divalent catti. Apparently those same proteins will transport lead as a facilitated transport. They do inhibit or prevent the free diffusion of lead from the blood into the brain. There is a facilitated transport mechanism which can, if you will, be fooled into taking lead across.

Q When is the blood brain barrier formed in the human body? Is it there from birth?

A It's there perfectly from birth as far as we understand. It is certainly fully in place by approximately 10 years of age, but functionally it is partially in place by birth, yes.

Q Would the absence of the completed blood brain barrier be reason to believe that greater amounts of lead would enter the brain in the young child than the adult [25] A I don't think so. It used to be, but I think now it's probably because the immature brain is taking up calcium more rapidly than the mature brain, and that it's a difference in the rate constance of the calcium transport system that influences the more extensive uptaking of lead by the immature brain rather than the incomplete blood brain barrier. That used to be the dogma, but I don't think it's true any more.

Q What you are saying the result is there but the cause may be different from that you originally believed.

A That's correct.

Q There is a greater amount of lead entering the brain of the child.

A There is still a greater amount of lead that enters the brain of the young child, but probably not because of this blood brain barrier, which is what people referred to five years ago.

Q You referred to the development of the brain during the last trimester of pregnancy.

A That's right.

Q What are the dangers to the fetus of lead [26] exposure or lead absorption during the first two trimesters?

A Very early in pregnancy, really physiologically before pregnancy can be said to even begin, relatively high doses of lead, at least in animals, have been shown to interfere with the implantation or the attachment of the fertilized egg to the womb. Again, relatively high doses of lead in the first trimester can cause spontaneous abortion of an embryo.

In terms of other risks to the fetus during relatively early exposure, these seem to be very unclear. Lead does not appear to cause structural abnormalities in mammals. It can cause terata, that is, structural defects in chicks, but it is not, in my opinion, a classic teratogen, morphologic teratogen in mammals. It is difficult, I would point out, to make clear separations in early and late terms exposure of the fetus to lead because of the long residence of lead in the body. That is, a woman may be exposed to lead early in pregnancy and deficits noted in the child after birth, but those deficits might have been associated [27] with the on-going exposure which occurred in the late stages of pregnancy rather than the late stages.

Q When you talk about on-going exposure, would you be referring to the environmental exposure or the internal?

A I'm referring to the internal exposure.

Q Even if the woman were removed from the environment of lead exposure, there still would be exposure in the later stages in pregnancy of the fetus.

A For all purposes there is a continuing exposure to lead even after removal from sources of lead, yes.

Q How long does that continued exposure last after removal?

A If it were possible to take a person into a lead-free environment after an episode of exposure, the turnover of lead is probably in the order of 100 days. So within a year or so there would be a reduction in lead.

There is also, of course, a rapid removal of lead from the blood into the bones in soft tissue that is no longer available for circulation. But considering [28] that most people are not removed to lead-free environments, even if they go from areas of relatively high exposure to lower exposures, there is continuing cyclic and exposure to lead. That was certainly my observation in looking at the records from the secret service.

Q When you talk about continued exposure, that would be even if they were removed from any occupational exposure.

A That's correct. All persons in this world are continually exposed to lead.

Q Let's go back to the study that you mentioned concerning the damage to the male reproductive system caused by lead.

A Yes.

Q In that regard you first of all talked about the heme synthesis effect on the liver which then had an effect on the reproductive system. Could you elaborate on that?

A This primarily effect the on the sex steroid metabolism. The liver is the major organ which metabolizes the endogenous sex steroids. The metabolism [29] of sex steroids is a heme dependent process; that is, many of the enzymes and co-factors involved in steriod metabolism contain heme. If there is an inhibition of heme synthesis, which is one of the primary biochemical regions of lead, then all functions dependent upon heme, all biologic functions are effected, then one of those has been shown here as well as in a wide range of animal studies including some of my own is hepatic metabolism including those pathways which metabolize the sex steroids such as testosterone, estrogen. That would be one of the major mechanisms by which blood would effect reproduction in both sexes.

Q What would be that effect actually?

A That effect appears to be decreased levels of circulating testosterone and a change in the sensitivity of testosterone receptors in the gonads. Work on receptors has been done by Thomas and Brogan, published in 1982.

Q What is the effect of that?

A The effect, essentially, was to reduce the rate at which sperm mature and are produced, so the functional effect would be eventually infertility in [30] men.

Q Would that be a permanent effect?

A If the lead is there permanently, yes.

Q If the individual were removed from the high lead environment and going back down to a lower level, would it be reversible?

A It might be. It's unclear whether or not the lead would then be removed from the liver and also from the gonad itself. Lead can obtain entrance to the male gonad and, in fact, effect steroid metabolism in the gonad itself.

Q Is it possible to measure the effect on heme synthesis?

A Yes.

Q How would you do that?

A There are several ways. You can measure the circulating blood cells. And, in fact, one of the standard clinical tests for lead exposure for measurement of ZPP, FEP, technical known as protoporphyrin-9 is a measure of heme synthesis in the red cells.

One can also measure the status of hepatic metabolism which was done by Alvares by administering a [31] standard agent such as antipyrine and measuring its clearance in the body by taking serial samples in the blood. That is a standard clinical measure of the status of liver metabolism, and what Alvares has published is that lead exposure didn't heme metabolsim was measured this way in humans and men who were occupationally exposed to that.

Q If these tests for effect in the heme synthesis were performed and showed no effect, then I assume there is no effect in terms of the reproductive system as it relates to the liver.

A No, because the ability to test hepatic metabolism in this manner in humans is very sensitive. It would not be a clear cut answer that liver metabolism was unaffected by any experience, lead or otherwise. It's a very gross measure, and, in fact, if a significant increase or decrease in antipyrine disappearance occurs, then you really have a major effect on liver metabolism. It's not a sensitive measure.

Q Certainly, as the ZPP shows, that there was an effect on the metabolism you would have a greater [32] concern.

A The ZPP effect, yes. That's if you will, a measurement of an analogous compartment. You are measuring now the effects of lead upon heme synthesis in the red, cell not in the liver.

Q Would you expect a similar response in both places?

A Yes, I would. In fact, research would suggest that the liver and kidney are very sensitive to the heme pathways in those organs are very sensitive to lead one can take them out of the animals and look at them.

Q What is the test for ZPP that is actually referred to as ZPP?

A Yes, it can be called a ZPP test. Hemotometer test it is sometimes referred to.

Q If that test were performed and showed no effect, whatever the blood level might be, would that also indicate to you there was no effect on the liver as well in heme synthesis?

A Before I think one can completely exclude that possibility, I think it would tend to suggest that, but [33] before you would completely exclude that possibility you would have to know the history of lead poisoning first.

Q But if one were testing on a regular basis for ZPP, assuming the history were also available, would you be able to test for the effects on the reproductive system as it is caused by the heme synthesis effect on the liver?

A Not completely, no. You are measuring an analygous compartment. Again, I should point out most of the instrumentation applied clinically for screening basis is not that sensitive. I can only measure reliably increases in ZPP that are at least two standard deviations above, so it is not as sensitive as actually looking at hepatic heme metabolisms.

Q How would one do that?

A Ideally by doing a liver biopsy.

Q From a practical point of view, on a regular basis that couldn't be done.

A I don't think one would do it on a regular basis. That's why one measures blood lead. You don't biopsy the organs blood effects. You measure internal concentrations and hope to in a preventive fashion keep [34] levels of exposure sufficiently low so that the levels in the site of actual toxic effect are not exceeding unacceptable effects.

Q When you talk about measuring blood lead, is there a difference between blood lead and lead effect?

A Yes. Blood lead is not an effect of lead. Blood lead is a concentration of lead inside the body.

* * * *

[42] Q You originally identified the level at which adverse effects occur to the reproductive system as 25 to 35 ug/dl.

[43] A That's correct.

Q The studies that you referred to, with the exception of Deknudt, all seem to be reporting on essentially higher levels.

A No. I described several mechanisms by which lead could effect male reproduction, and I think you will recall for two of the mechanisms, that is, hepatic metabolism in sex steriods and chromosomal effects, those effects were, in fact, observed at relatively low levels of lead exposure. It was the later effects that we were talking about on hormones on circulating hormone levels and sperm shaped where the effects have been described at relatively higher levels.

Q Getting back, so I understand, the effects at the relatively low levels are what?

A Are primarily effects of hepatic metabolism on steroids and on chromosomal integrity as measured in lymphocytes.

Q The studies that you rely on in respect to each of those effects?

A With respect to the hepatic metabolism, there are a large number of animal studies, including my own [44] work, and the studies in humans are primarily the studies by Alvares.

Q In terms of the animal studies do we have a way of equating the blood lead levels from the animals, studies to humans?

A Probably not extremely useful to equate blood lead levels but rather to look at a comparability of effects. In animal studies, again, were you can take tissues out and study them, alternations in hepatic metabolism occur relatively rapidly and can be associated with blood lead levels in rate of 15 to 20 UG/DL.

Q From that can you conclude that levels of 15 to 20 UG/DL in humans you would have similar effects?

A It would be hard to say, but I would conclude that based on the knowledge of the sensitivity of that pathway to lead that the effects would start to occur at very very low levels of lead exposure. This is a very sensitive system and one of the first to respond to that.

The liver accumulates a great deal of lead in adults and children after exposure, so there is no reason not to expect the effects starting to occur on a [45] linear basis at very low levels of exposure.

Q In terms of the chromosomal activities as measured in lymphocytes, I believe was your statement.

A Yes.

Q What studies did you rely on?

A Deknudt and Schwanitz. As I said, there are others that are now confirming these effects.

Q Do you recall the names of any of those?

A Bainio, and I think that's it. That is the one I can recall at the present time.

Q The Deknudt studies is the one we discussed in 1977.

A Yes.

Q How about the Schwanitz studies?

A Schwanitz is very similar. I think it was published in 1978.

Q What was the nature of that study?

A Again, looking at the population of workers and looking at lymphocyte and chromosome status.

Q At what level?

A I think Schwanitz may have collected some people down as low as 35 UG/DL.

[46] Q What did he conclude with respect to that level?

A That there were significant effects of the frequency of chromosome abberation.

Q What are the consequences of those effects?

A As I stated, the consequences of those effects are generally considered by biomolecular biologists to either be associated with increased risk of cancer or increased risk of heritable genetic disorders, infertility and fetal death.

Q Would that be just in the males?

A That's all they studied were males.

Q Would there be reason to believe there would be a difference in females?

A Not that I know of, but as far as I know no one has ever looked at lymphocytes and chromosomes in females.

Q I believe the other study you mentioned was Govoni.

A It's a very similar study of smelter workers, I think were studied. Part of a long series of investigations that Govoni has been doing looking at [47] exposure in the industry and alterations in chromosome integrity.

Q At what levels did he study?

A I don't think those were reported, but I would say that these are studies done in Finland, and if you look at data from Seppalainen and Hernberg who have been studying the same industry in Sweden, the blood

lead levels in those industries are very low, in the order of 20 to 30 UG/DL. The Fins have had very stringent controls on lead exposure in industry for quite some time.

Q Going back to the hepatic metabolism, would there be comparable or similar effects in females?

A There may be.

Q Any reason to believe it would be different in males than in females?

A Yes. I have data on animals which suggest there are differences between males and females in that the females are much less responsive. These are rats.

Q In terms of the Alvares' study, which is the one you referred to there, what levels are we talking about?

A I believe the blood levels, they were [48a] relatively small studies. I think it was demolition workers who were exposed to lead through welding primarily and I think the levels were in the order of 45 to 60 UG/DL.

Q When was the Govoni study?

A The first study was done in 1979. Govoni has written a book which summarizes most of his data which was published, I think, in 1983.

Q Going back again to the fetal exposure. In the very early stages of pregnancy you indicated that relatively high doses of lead can interfere with implantation and spontaneous abortion.

A That's correct.

Q Any other effects that you believe occur from exposure to lead in the first two trimesters?

A I don't think so. I think the effects which have been observed are related to late stage exposure.

Q How about central nervous system effects?

A Those are primarily related to third trimester at the point in which the complex development of the nervous system occurs.

* * * *

[49b] BY MR JASPAN:

Q Going back to my last question, I didn't get your entire answer. Am I correct that there is some development of the central nervous system during the first trimester?

A Yes, in the sense that all cells of the body are derived from the primordial cells, yes, but lead doesn't appear in those stages of neural crest? Development but rather with the period of synaptogenesis in complex differentation of the nervous system as far as I know.

[49] Q What generally were your conclusions with respect to prenatal exposure in those studies?

A Our general conclusions were that the effects of lead prenatally were very similar to the effects postnatally.

* * * *

[50] Q With respect to the central nervous system?

A With respect to the central nervous system, correct.

Q In generally what are the effects postnatally?

A To cause substantial irreversible cellular and functional damage to the brain.

* * * *

[54] Q Did you identify Terata?

A As I mentioned earlier, with the exception of the chick I don't think anybody has found Terata physical abnormalities associated with lead exposure. Needleman in his most recent paper has suggested an increase in the incidence of minor physical abnormalities associated with cord blood levels, but those may well be markers for the nervous system effects. There is a good degree of correlation between minor physical abnormalities which he described and the nervous system deficit. They are not major structural abnormalities. They are things such as small birth marks, hydrocele [55] and, in a large part, reversible effects which are observed at birth on careful examination.

* * * *

[56] Q What has been shown in terms of effects on offspring of exposure of the parent?

A As I stated, with the environmental studies and occupational studies of women, it's important to note that the lead status of their male partner was never determined. In the Nordberg studies which observed an increase in the rates of spontaneous abortion in women living near smelters, these rates were, in fact, even higher in these women's husbands—they were all married couples—who were employed in the smelter. Of course, in all cases, the men were living with the women, so there was co-exposure although the men's exposure was not investigated as thoroughly as the women's exposure.

[57] At much higher levels, as I mentioned before, lead can be an abberation, that is, actually induce abortion during the first trimester of pregnancy. These are at very high levels of lead exposure. Common, perhaps, in pottery industries in England before 1900. Certainly nothing relevant in industry today. I don't think anyone in the world, possibly.

Then the studies by Needleman which would suggest that blood status at birth related to prenatal exposure is associated with deficits in intelligence and behavior in children.

Q Prenatal exposure could be exposure to the fetus.

A That's right.

Q And possible exposure of the adult.

A This was measured as exposure to the fetus by measuring the cord blood which is the fetal circulation.

Q Are there any studies showing the exposure of the adult male has an effect on the offspring?

A Only, I would say, the studies of women which have not looked at the male such as the Nordberg studies where one could recently infer that the men were equally exposed. There have been no studies in which the women [58] were only exposed.

Q Were there any studies showing where only the men were exposed and the effect on the child?

A No. I don't know those have ever been done, either.

* * * *

[66] Q Would you expect similar type results in prenatal fetal exposure?

A No. I'm not sure. Because the specific neurochemical pathway we are looking at is not completely linked down prenatally, so I'm not sure of that.

Q Earlier I asked you this question. What is your answer for those organs you believe to be more sensitive to blood lead exposure. That included heme synthesis, but you named several others.

A Heme synthesis, calcium metabolism including that involved in the brain, the heart and I think I added that these would be the most sensitive systems. Probably also the immune system.

Q The immune system.

[67] A Yes.

Q With respect to each of these, the sensitivity in the child would be greater than in the adult.

A Possibly calcium metabolism, but I'm not sure of that. I'm actually looking at calcium metabolism in osteoporatic women. So I'm not sure of that. I don't know if it would be. I'm not sure of it's an issue of sensitivity. It's an issue of access. More lead is absorbed by the children, but the target site may not be different.

Q You say more lead is absorbed.

A That's true, yes.

Q From the blood into the—

A From the gut into the blood, number one. And there may possibly also be a different distribution of blood once it's in the blood among the various organs in the child as compared to the adult.

Q At a certain blood lead, 25, you might be concerned with respect to all four of these organs in the adult.

A I would definitely be concerned, yes.

Q I assume at the 25 blood lead level you would [68] also be concerned with the child.

A I would be concerned for anybody that has a blood lead level of 25.

Q The concern would be different in the child than in the adult.

A It might be in that the expression may be different. For instance, in the area of calcium metabolism there is data now that suggests that the growth and stature of children is affected by blood levels of that order, 15 to 25. I wouldn't expect that to occur in the adults as the adult's growth stature is through.

We have some data to suggest that lead may exacerbate osteoporosis. With respect to the heart, the only data I have seen relate to adult men, and effective levels as I said in the range of 15 to 25 in the Pirkle studies, I haven't seen any description of the effect in children. I don't know enough about cardiovascular physiology to say this may be age related or just that people haven't looked in this area the same way. The blood pressure in children is so relatively labile that it's impossible to determine [69] whereas it is more stable in adults.

Certainly with the effects of the nervous system, calcium metabolism as it is expressed in the nervous system, I would expect it to be different, at best. Whether one would be more sensitive or less sensitive, I don't know. Dr. Baker and Dr. Hanninen, in their work on lead workers and neurophychiatric function, have found effects at levels similar to those that Needleman has found in children. There are different kinds of effects and not so much effects on learning and behavior as they are on mood and short-term memory, but they may be the same lesion in the brain.

* * * *

[70] Q With respect to the child we talked about the central nervous system.

A Yes. We talked about calcium metabolism, too, in terms of growth and stature and osteoporosis.

Q Okay.

A And we talked about the heart in which I said I didn't know anything about the sensitivity of the heart in the child, there there is very good evidence now of the sensitivity of the heart in adult man.

Q The damage to the central nervous system in the child, am I correct in understanding it would be permanent?

A Damage to the central nervous system in any human is permanent because the central nervous system does not replace itself.

Q What about heme synthesis? Is that permanent or reversible?

A Theoretically it should be reversible in that it is an effect on enzymes which can be resynthesized; however if lead continues to be present the effect persists as long as lead is there.

* * * *

[72] Q Are you familiar with the fetal protection of policy of Johnson Contols?

A I have read it.

* * * *

[74] Q Is there reason to treat the fetus or the small child different than the adult?

A There may be, but only at blood lead levels below 10.

Q You are saying that everyone should be about 12, and then you can talk about finer distinctions.

A Exactly. I think there may be, based on Needleman's data, reason to suspect that the fetus may be sensitive to blood lead levels as low as 6, so if we reach the happy point at which we can talk about those levels existing in this country, then we can talk about differential protection of the fetus.

Q If I understand your position, everyone should be below 12.

[75] A That's right.

Q And then—

A That's not just my position, but the position of the public health service and EPA.

Q That everyone should be below 12.

A That's correct.

Q And then we could possibly talk about finer distinctions in the fetus and the adults.

A That's correct.

Q The small child and the adult.

A That's correct.

Q But any policy that doesn't aim at getting everyone below 12 you find inadequate.

A It's difficult to find a distinction. For instance, based on the Pirkle data, there is very substantial risk of hypertensive heart disease which, after all, heart disease is the number one killer in the United States. There is a very substantial increase in hypertensive heart disease in the adult man with blood lead levels between 15 and 25. I don't see why one is ignoring that risk to men and focusing, say, in this policy, on the fetus.

[76] Q Concern with the heart is the Pirkle study?

A Yes.

Q When was that published?

A That was published in 1985.

Q According to that was there any studies showing the concern for the heart?

A Yes. There were a range of studies but there was never a study of having the advantage of looking, number one, at such a large population, and, number two, at levels that were so low, and, number three, being able to control all the other risk factors for cardiovascular disease. This is part of the data developed by the national health and nutrition examination survey conducted from 1976 to 1980 of the U.S. government. In my opinion, this is a major epidemiologic study conducted on thousands of men, women and children, and not only did it investigate lead status in the general population but also looked very specifically by design at a number

of risk factors for diseases including the so-called Framingham risk factors for cardiovascular disease.

So in the analysis Pirkle was able to separate [77] those risk factors out and show the major role of blood lead elevation in increased risk.

* * * *

Q I assume you are familiar with the CDC 1985 statement on blood poisoning in children.

A Yes. I was part of the committee that worked on that.

* * * *

[81] Q Assuming that you were advised by those that [82] are experts in occupational hygiene and engineering controls that it would be impossible to accomplish at least at this stage, would you disagree with the treatment of the fetus in providing extra protection for the fetus which may not be provided to the adult?

A I don't think that it's extra protection. I think that at these levels everyone is at very severe and significant risk, male, female or fetus. So I don't see any protection being provided here.

Q But you would agree, then, that even in walking the streets of Washington, D. C. all three categories of people would be at risk.

A They are clearly at risk, but this is of a more excessive risk you are talking when you are talking of blood lead levels of 30, 20, 29, 40. These are levels in terms of biomedical, in terms of huge excesses for all three organisms. So it's impossible for me to decide whether it's worse for a child to be born with some neurologic detriments or a man to have hypertensive heart disease. I can't make that choice. I wouldn't know what I would choose. I have children. I have a husband. I don't know which one I am going to knock [83] off.

* * * *

[99] Q How do we measure blood lead levels in the fetus?

A As far as in know, knowone has measured blood lead levels in the fetus. It is possible that with nuclear magnetic spectroscopy that it could be done.

It is also possible, people are measuring fetal circulation now for genetic diseases, and it could be done. There is no barrier to it.

Q Is there an indirect way that is done by using the mother's blood level?

A I don't know how that would be. You can measure the mother's blood lead level.

Q Isn't it assumed that the blood lead level of [100] the fetus is similar to the blood lead level of the mother?

A It has been assumed, but there is actually very little data on the subject, and there is other data that would not be the case.

Q Which data is that that would suggest that would not be the case?

A Barltrop, Wiberly, Delves. I just reviewed this whole literature for a paper in the press. There is a range of studies that have looked at this, and RYU. It's not clear that maternal blood is an indicator of fetal blood of that concentration. That has been kind of a dogma statement, like the blood brain barrier statement, but it does not appear to hold up too well upon examination.

Q Aren't there also statements that support that?

A Very few.

Q Needleman?

A No. Needleman did not measure the mother's blood lead level at the same time they measured the cord blood level. That is not what they are saying. The [101] Needleman and Rabinowitz study of cord blood levels. That is not the fetal side. As a matter of fact, I talked to her about this because those levels are very low, and they would suggest that fetal blood leads are lower than maternal. If you recall this paper I the Journal of

American Medical Association, the blood leads in the cord blood, he had leads found at two, one group goes from two to seven, and another goes from eight to nine. These are levels based on the national survey that are very, very low particular for this population of Boston women he has been following.

He did not measure the blood lead at the same time, and I think it would be very interesting to know what the mother's blood level would be. * * *

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[102] Q We talked about blood lead and we also talked about lead effect. I assume it is much more important what the effect of the lead is than the actual quantity.

A Obviously, one expects them to be correlated, at based on a general dose response there is a theories of toxicology, but what we are interested in are the effects of lead.

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[EXCERPTS OF LEGATOR DEPOSITION]

(Jones Aff., Ex. C)

[11] A. There are very few chemicals that we know of, perhaps you can count them on the fingers of one hand, where there is evidence that would indicate the exposure to the male has an effect on spermatogenesis which can then be transmitted to the progeny, to the F-1, the children.

And DBCP, although we don't know in terms of the transmission of genetic damage, is certainly suspected of doing that. Vinyl chloride is a chemical that, again, as far as we now know, can increase spontaneous abortions and lead falls into this group of chemicals that has an effect as far as we now know from the literature, on spermatogenesis.

* * * *

* * * The literature on lead—first of all, let me preface my remarks by talking a little bit about our human studies, what we can and cannot do and probably the big emphasis on what we cannot do in human epidemiological studies.

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[13] Probably in terms of our epidemiological studies as to transmissible genetic damage, the only information that we can generate, because it's something that we can get to fairly easily, although it's pretty damn inexact, is an increase in spontaneous abortions.

[14] And an increase in spontaneous abortions is somewhat comparable to tests that we can run in animals where we get a reduction in litter size, or where we get a failure of the conceptus to develop, these kinds of things.

So, given all that, the reason I went through this long lengthy description, is to indicate how difficult it is to get this cause and effect in people when we talk about male-mediated damage effected during spermatogenesis. And in the total sum of literature available on this area,

we know of very few compounds that can indeed or allegedly seem to cause effects in the progeny when the male is exposed.

And to be directly responsive to your question, in terms of lead which is one—which forms as one of the members of this very select group of chemicals, and I think I can tell you very quickly the chemicals that we suspect or have evidence of male-mediated effect would be lead, dibromochloropropane, kepone, vinyl chloride and possibly anesthetic gases. That's the sum total of chemicals that we know of where there is information about the male-mediated [15] effects.

Now, there is a variety of studies with lead that go back to about 1860 actually, that would indicate an increase in spontaneous abortions from male exposures. Now, again, the male—and I can give you—I have the references with me, and I can just read them off very quickly.

In 1930 there was a study by Torelli, where he found an increase in abortion rate. As I recall that study, it was about a three to four fold increase over control. There was another study in 1905 by Tardieu, in lead workers where, again, he found an increase in spontaneous abortions.

There was a study in 1905, by a Frenchman, Rodeaux, who found, again, an increase in abortions. And we have some fairly current studies that were, in 1975 to 1979, where, again, we have shown an effect in terms of fertility and sterility on male workers. And my major interest here is male workers.

Q. What were those studies in '75 to '79?

A. That's the Lancranjan studies which I am sure you are familiar with. I have a copy of it with me. [16] Now, so that kind of warms the constellation of studies that we have in humans.

And I think it's fair to say that when we look at spontaneous abortions, this is not a very satisfactory end point. And the reason it isn't the satisfactory end point is because we are looking at lethality. And from a gentic

point of view, lethality, of course, is the end and we are no longer interested in it because that's it in terms of transmission.

But I think the thing that one has to keep in mind, is that for compounds that produce spontaneous abortions at one level, okay, at substantially lower levels one would anticipate a variety of adverse genetic effects.

So, when we talk about spontaneous abortions, we talk about sterility when we are talking about effects directly on the sperm. Then one would suspect that at lower levels, we probably would find the viable transmissible genetic damage.

So in some respects, and we have been through this with dibromochloropropane, in some respects, the higher concentration that leads to lethality of the embryo, is probably of [17] less concern than lower concentrations where you get viability and genetic problems.

Q. Are there any studies that indicate with respect to lead, specifically, those problems?

A. Yes. Yes, there is. In fact, the lead studies started a whole area of research, as far as I was concerned through my own personal deal, and—first of all, in the animal studies there are a number of studies which are comparable to what we have seen in the human population in terms of reduced litter size and all this kind of stuff.

An interesting study by Brady and Zenick is another author. I do have the reference with me and I'll leave that with you. This was a fascinating study because it was one of the few that I think were attempted to look at the possible adverse effect on viable progeny. And what these investigators did, is they administered the chemical, lead, to males only, females only, or both. Okay? And then they did a series of tests on the resultant progeny.

They exposed the males or females, mated them, and they they looked at the offspring. And what they found was that with the lead exposure for males only or females only or [18] both together, that they showed a behavioral

anomaly as manifested by one of the tests that they used which is one of the fairly standard tests that behavioral toxicologists look at, and that's swimming tests. It was in rats, as I recall.

* * * *

[19] And another piece of evidence that would indicate that with lead, we are specifically talking about a genetic effect, would be the ten—well, actually let me say that there are about fifteen or sixteen cytogenetic studies that have been done with lead in humans. That's, you know, this chromosomal work I talked to you about earlier. And we now have ten positive studies that would indicate that lead in occupational exposures, caused chromosome damage. So, if—

Q. That's in humans you are referring to?

A. Yes. This was in humans. This is one of the things that we can do. It's not a transmissible genetic damage, but it's one of the things we can do.

So, given the sum total of information we now have, I think one would have to conclude, and there is a number of experts that are far greater experts than I in lead [20] toxicology, who have also concluded that lead has a male-mediated effect, that lead affects spermatogenesis.

And this is given the severe limitations that we have on experimental studies both in animals in this difficult area of toxicology. And then one further thing, of course, that's always of interest is when we talk about spermatogenesis, we are talking about a very active process of cellular division. And we know that with most of our chemicals and radiation, that the dividing cells during the spermatogenic cycle are quite susceptible to chemical damage.

So, putting the whole thing together, humans, animals, including cytogenetic information we now have, I think that one would have to conclude that lead is one of the very few chemicals and probably one that has been studied to a great extent, that probably causes a genetic lesion during spermatogenesis.

* * * *

[25] Q. But that we don't know for sure at this point?

A. Well, we have animal studies and by the only criteria that we have been able to generate in human studies —by the only criteria we have been able to generate in human studies, we find, indeed, that lead gives us that indication that we can measure.

* * * *

[47] Q. Again, going back to your familiarity with the literature on lead. Are you in agreement that whatever level is dangerous to the human—appreciating the individual variability—that the children, the young children are even more sensitive to lead than are adults?

A. No question about it. Certainly. I am in total agreement with the sensitivity. In fact, I don't think we have even been able to reach that concentration that one could say has no effect on kids at the present time. If you look at some of the recent work, there is no question about the sensitivity of children to lead, no question.

Q. Greater than the adult?

A. Sure.

Q. Why is that?

A. Huh?

Q. Why are children more sensitive?

A. Possibly because we are talking about [48] developmental systems, we are talking about fast growing cells, we are talking about the difference of deposition and mobilization of lead.

There are three places, three pools, really, that lead is accumulated in. One is the blood, very short term accumulation here; the other is in soft tissue, intermediate. And finally it's in the bone deposition.

And when you look at developing children, I think you have a rapid turnover, and one would anticipate that with something like lead, you probably would get some serious adverse effects, and that's what our current literature would indicate. There is no question about children being very sensitive to lead.

Q. Whatever standard might appropriately be set for adults across the board in terms of the body systems, that even a lower standard if one were setting one, would have to be set for population of children?

A. Well, from—let me preface this by saying: From what we now know, it would certainly seem that children are far more sensitive. On the other hand, we are talking about unfortunately [49] great areas of profound ignorance.

For instance, I could not tell you on the basis of the literature, I could not tell you, what would be a safe standard in terms of male-mediated effect. I don't know. It could be in the area of what we see as affecting children or it may be significantly higher, I don't know.

But, certainly, on the basis of the information we now have, epidemiological, recent vintage, you know how recent some of those studies are, within the last several years, we have very serious concern for the effect on children. If this concern should be transferred to other areas of toxicity, I don't know, but we certainly have the indications that children are very sensitive to lead.

Q. And extrapolating further, are you in agreement with those who conclude that the fetus, in utero, would be as sensitive or even more sensitive than the small child to lead exposure?

A. Again, there is no question about the sensitivity of the fetus. There is no question about it. I mean, I don't think one could argue about the fact that lead affects the fetus.

Q. At least based upon our current knowledge, [50] appreciating what you described as a tremendous amount of ignorance—

A. Yes.

Q. —that the level that would be set for fetal exposure in utero, would be lower than generally might be appropriate for an adult? Based on the current literature and based on your current knowledge?

A. Yes. But what I am trying to say, as we have—you say indications—there is no question about, you know, the effect on children, the effect on the fetus.

We now have indications of the effect on the male. And I don't know how the three would compare at the present time. So, I'd say that there is no question about the high sensitivity of the fetus to lead toxicity in young children.

As far as the male-mediated stuff—how sensitive is the entire process of spermatogenesis to lead? I don't know. The only thing we can say right now is we know from all indications we see, that there is a problem. I can't give you the rank order, unfortunately.

Q. Let's talk about what we do know. Lancranjan's [51] lowest level at which he found any type of effect was the 42 microgram average group?

A. Yes. But the problem there, as I tried to indicate, we only see gross abnormalities in the sperm, okay? When I talk about transmissible genetic damage, I'm talking about perfectly normal, as far as we can see, sperm, that have a genetic lesion that was induced in the stem cells which is later manifested by abnormalities such as behavioral anomalies.

Let's face it, in our population right now, over one third of the mentally, retarded are there because of genetic reasons. What percentage of that is due to chemicals, I don't know. But it's a tremendous background rate we have of that. And, you know, who is to say what part lead plays in that, because lead after all is in our everyday environment.

So, when we look at the studies that we now have with the insensitive indicators that we now have, then one would—from what we know about the relation of concentration times exposure equals effect, from what one knows about that, one would expect effects substantially below what has currently been studied in these [52] epidemiological studies to indicate the transmission or genetic damage to viable—

Q. We have no studies that indicate that yet?

A. Oh, yeah, we do. We do. We have the study of Brady in animals is one where we have indicated a behavioral deficit right there. Sure. Male mediated. We do.

Q. We have the studies that indicate the transmission through the male—

A. That's right.

Q. —of the problem. I'm talking in terms of levels in humans, that's what I am referring to at this point. We don't have the studies that would indicate at what level?

A. And we probably never will have because of the very nature of the problem. Now, you see, this is kind of—we have almost the same kind of discussion with dibromochloropropane.

With DBCP we had substantial information about the fact that this chemical at five parts per million caused testicular atrophy in a variety of animals. The study was generated in 1963. And basically we ignored the animal data, until the workers found ān effect themselves in 1977.

[53] So, one of the problems I think that we often have in this field where we are very limited in what we can do in people because of the very nature of the problem, is we simply have to use animals as our surrogate, as our indicator of potential toxicity. And based on that, we're a little bit worried about the effects of lead even at very low concentrations.

* * * *

[59] Do you have a disagreement with this policy to the extent that it provides or isolates out those women capable of bearing children from the rest of the population? Recognizing that the desirable end would be to reduce the entire population to a level lower than the OSHA standard.

But to the extent that that's not technologically feasible, do you agree with the concept based upon the known

evidence, that isolating out this population, makes sense?

A. Let me respond to it on a very personal level. If I had a daughter of reproductive age, I would not want her to be exposed to any concentration of lead in the work place that, you know.

[60] If I had a son of reproductive age, I likewise would not want him to be. So, what I, you know, stated before is that it looks to me based on the information that we have, that the process of oogenesis, spermatogenesis, are sensitive to lead. The amount of sensitivity is yet to be determined in all cases. And, therefore, I would like to see every precautionary measure taken, if at all possible, to limit exposure to both groups.

And I don't really at the present time have enough information to really weigh the comparable sensitivity other than to indicate that I think it's bad for both.

* * * *

[63] Q. Am I correct in understanding that the literature does know with better certainty the levels at which the small child, and by extrapolation, the fetus, is in danger?

A. Right.

Q. Well below the current OSHA standard?

A. Exactly.

Q. And, certainly, you would agree that the knowledge of those safe or unsafe levels, if I can use that terminology, are well-documented and known with respect to the fetus and the small child; whereas, when we are dealing with the spermatogenesis type problem, we are still dealing, based on current literature, in an unknown in terms of the precise levels?

A. I would agree with that statement. I would certainly agree with that statement.

* * * *

[64] Q. Now, the basis upon which you conclude, as you have, that spermatogenic effects are experienced under the current OSHA level, based primarily on the Lancranjan study; is that correct?

A. No. If we look at the sum total of studies that go back to 1860, where we see that male exposure [65] lead to spontaneous abortions, okay, then we'd have to look at that, plus, the Lancranjan study.

But spontaneous abortions stand out even to a greater extent than what Lancranjan found, because in the spontaneous abortion bit, we had the developing conceptus, okay, growing to a certain level, and then dyin

So what we had here was a population of sperms that were able to penetrate and are able to generate the development of—the initial development of the fetus. And then later on, we got reabsorption which resulted in spontaneous abortion. Now, that kind of effect, okay, one would anticipate that that kind of effect is indication of genetic damage where we have affected the stem cells and was later carried over.

* * * *

[66] So, you know, you have a spectrum in terms of adverse effects versus concentration. And what we now have with lead in the human population, we have the abnormal sperm, we have several studies on spontaneous abortions, and that's as far as we can go in human studies.

We simply do not have the techniques now because of a high background rate, noise level, to see if indeed, the kids of lead workers, in this generation or subsequent generations are mentally retarded or what have [67] you. We just don't have the wherewithal to do that kind of study.

But what we do now see then, is the things we can measure in people plus what we can do in animals which would indicate transmissible genetic damage. If you relate that to concentration, you can see that what we can measure in people is at a much higher concentration than the kinds of things that we can't measure, and where we have to rely on animal data.

* * * *

[71] Q. * * *

I understand that you gave us a long list of studies earlier that support your position that, in fact, lead causes spermatogenic—I'll get these words right, eventually—effects.

But I am focusing specifically not on the general proposition, but on the proposition of evidence currently available as to what level this is likely to occur, and particularly the conclusion that it's likely to occur at levels well below or below the current OSHA standard. And on that, you say the [72] Lancranjan and Braunstein, I guess?

A Lancranjan, primary. And the other part of the concentration question has to look at the animal studies where we can do measurements that we can't do in people. And only then do you reinforce what we see in the limited, very limited human epidemiological studies; so, we reinforce that with our animal data. But we carry it one step further where we show that there indeed is a male-mediated effect on spermatogenesis which should give us progeny with some deficits.

Q. But in terms of a level, we are focusing on a level —we can't equate the exposure level in animals to the exposure levels in humans?

A. The only thing one can say is not certainly—quantitatively, we can't do that. But we can say that from what we can see qualitatively, we know that the levels that cause the deficits in the progeny were substantially below those levels that would adversely affect the outcome in terms of lethality such as reduction in litter size.

Q. Any other studies just, again, so the answer is complete on the transcript, with respect to this issue of a level? Braunstein, Lancranjan, and [73] the animal studies indicating, as you refer to them, as qualitatively that the levels at which there would be that spermatogenic effect would be lower than the levels that reduce litter size on the other data?

A I believe at the present time that's all I am aware of.

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DEFENDANT'S RESPONSE TO PLAINTIFFS' FIRST INTERROGATORIES TO DEFENDANT

(Jones Aff., Ex. D)

* * * *

INTERROGATORY NUMBER FOUR. For the entire Battery Division of Johnson Controls, Inc., state the total number of lawsuits brought by or on behalf of the offspring of employees or former employees from 1976 to the present which lawsuits are or were based on claims of physical or mental injury to such offspring which resulted from the exposure of their mothers to lead in a Battery Division facility.

Answer

None.

* * * *

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

SILVERSTEIN AFFIDAVIT

* * * *

3. There is an extensive body of scientific literature that indicates the various risks of harm to adult men and women as well as their offspring and a developing fetus resulting from lead exposure. In my work I have been required to regularly review and evaluate the literature in the area of the toxic and other effects of lead on human beings.

4. Based on my work and review of the literature, there are scientific studies of both humans and animals that indicate an association between lead exposure and an increased risk of harm to human organic systems, including the brain and central nervous system, peripheral nerves, reproductive systems, kidneys and blood forming organs. There is also evidence of an increased risk of carcinogenic effects associated with lead exposure. On the basis of the animal and human studies it appears that the toxic effects of lead exposure on the reproductive systems of adult men and women include an increased risk of damage to the testes, ovaries and the germ cells (ova and sperm). On the basis of the animal and human data, damage to the male can include malformed and dysfunctional sperm, chromosomal damage and aberrations and testicular damage.

Defects in reproductive function that are associated with lead exposure include fetal death (spontaneous abortions and stillbirths), sterility, low birth weight, birth defects as well as developmental ab-

normalities in offspring. Some of these risks can be associated with blood lead levels in adult males and females as low as 20 micrograms per deciliter of whole blood. In my medical opinion there is insufficient scientific evidence to conclude that the fetus or offspring of lead exposed men are not at risk of damage to their central nervous system, including learning and behavioral capabilities. There is no scientific basis to conclude that the reproductive risks experienced by males or females are different in severity at equal blood lead levels. There is also no scientific reason to conclude that offspring are at greater risk if either the male or female parent has been lead exposed at equivalent levels.

5. In my medical opinion, the toxic effects of lead exposure on human adults is similar and equivalent in impact to that observed in children at equivalent exposure levels. There is evidence that male and female battery plant workers in Finland with blood lead levels as low as 21 micrograms per deciliter of blood suffer impairment of psychological performance, including such indicators of Central Nervous System disturbances as impaired memory and visual-motor dexterity. (See Exhibit A, attached hereto and incorporated by reference.) There is also scientific evidence of a significant risk of increased blood pressure in adult males and female workers with blood lead levels as low as 11.5 micrograms per deciliter for women and 16.9 micrograms per deciliter for men. (See Exhibit B, attached hereto and incorporated by reference.) Additionally, scientific evidence indicates that there is an increased risk of death from cancer of various types associated with the exposure of employees in battery plant as well as other lead exposure plants. (See Exhibit C attached hereto and incorporated herein by reference.) There is no evidence of a lead exposure level below which the cancer risk disappears.

* * * * *

BLOOD LEAD AND BLOOD PRESSURE

(Silverstein Aff., Ex. B)

Relationship in the Adolescent and Adult US Population

William R. Harlan, MD; Richard Landis, PhD; Robert L. Schmouder, MD, MPH; Nancy G. Goldstein, MPH; Lynne C. Harlan, MPH

* * * *

[p. 533]

Lead is ubiquitous in the human environment and has no known metabolic utility but does have a potential for toxic health effects. In this survey of the US population conducted from 1976 to 1980, there was a direct and linear relationship between blood lead and blood pressure. This association was statistically significant for systolic and diastolic pressures, and the effect was found at blood lead levels of less than 30μg/dL, which is the current "toxic" definition for occupational exposure.[22]

* * * *

[p. 534]

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No causal inferences should be drawn from this cross-sectional survey about the blood pressure effects of lead, calcium, and zinc, although these observations from the general population are consistent with extensive animal studies of lead toxic effects and trace metal interactions.

* * * *

Our analyses of the NHANES-II data provide a link between blood lead levels and blood pressure, but the cross-sectional nature of the survey limits inferences of causality.

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[22] NIOSH Recommendations for occupational health standards. *MMWR* 1983; 32:663-676.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Civil Action No. 84-C-0472

(Caption Omitted in Printing)

THIRD AFFIDAVIT OF STANLEY S. JASPAN

* * * *

2. Attached hereto and incorporated by reference as Exhibit A are true and exact copies of pages 1-2, 19-20 of the transcript of the deposition of Kelley Ann Brix, M.D., Assistant Professor of Occupational Medicine at the University of Michigan School of Public Health, that was taken by Defendant on October 17, 1985, in the above-entitled matter. Dr. Brix is one of the persons designated as an expert witness by Plaintiffs.

Dated this 1st day of October, 1986.

[Signatures Omitted in Printing]

* * * *

[EXCERPTS OF BRIX DEPOSITION]

* * * *

[2] Q. Will you state your full name?

A. Kelley Ann Brix.

Q. Your business address?

A. Department of Environmental and Industrial Health, University of Michigan, School of Public Health, Ann Arbor Michigan, 48109.

Q. I assume you're employed by the University?

A. Yes, I am.

Q. In what capacity?

A. I'm an Assistant Professor of Occupational Medicine and instructor of Internal Medicine and consultant in the Department of Family Practice.

* * * *

[19] Q. I'm asking your opinion based upon your review of the studies and whatever other bases you would rely upon, at what level do you believe there is evidence of adverse effect—what blood level is evidence of the adverse effect on the male reproductive system?

A. I think there is very strong evidence based on both animal and human information that above a blood lead of perhaps 60 to 70 that there can be an impact on the male reproductive tract.

Based on animal studies alone, it would [20] appear that there is an impact of lead on the male reproductive tract lower than that, as low as perhaps say 40 to 50 blood lead.

And it has shown to cause problems in certain species of animals but I cannot say that that's really the case in humans because we do not have good data in male patients, male subjects at those kinds of levels.

So I'm hesitant to make a statement one way or the other. We don't know.

* * * *